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Assessment of a Body Composition-Focused Approach to Obesity Treatment

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ASSESSMENT OF A BODY COMPOSITION-FOCUSED APPROACH TO OBESITY TREATMENT

by

Beverly D. Hall

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Each person whose signature appears below certifies that this dissertation, in his/her opinion, is adequate in scope and quality as a dissertation for the degree of Doctor of Public Health.

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ABSTRACT OF THE DISSERTATION

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Obesity is a significant United States' public health concern. However, high relapse rates continue to be a problem for obesity treatment programs while the focus remains on weight loss, not body composition change. This study examined whether a clinic-based obesity treatment program, focused on body composition change through resistance training, lead to improved body composition, exercise behaviors, and attitude change from focus on weight loss to body composition change. Improvements in self-efficacy, outcome expectations and stages of change were also examined. Forty-eight physician-referred overweight or obese adult women (mean body fat 41%, SD = 6.65%), completed assessments and questionnaires focused on body composition, weight, change in attitude, self-efficacy, outcome expectations, stage of change, exercise behavior(s) and duration at baseline and three months. This study used an experimental pretest-posttest design with random assignment to: 1) support group (n= 24) with required attendance to one Total Wellness Class and one Total Wellness Support Group class, or 2) support group plus individual appointments (n= 24) with attendance to one Total Wellness class,

one Total Wellness Support Group class and two individual appointments. Randomization to groups specifically examined whether there were differences in assessed items for those subjects who received group versus group and individual support. There were no significant differences between the support group only and support group plus individual support treatment groups at baseline or post intervention for any study variables. However, there were significant improvements across groups in attitude toward resistance training (from 22.31, SD = 3.45 to 24.25, SD = 2.72; $p \leq 0.001$), stages of change (from 2.44, SD = 1.01 to 2.77, SD = 0.99; $p<0.05$), outcome expectations (from 28.69, SD = 3.48 to 30.42, SD = 3.54; $p<0.05$) and days of the week exercised (from 2.01, SD = 2.0 to 2.71, SD = 2.13; $p<0.05$). Although there were no significant improvements in body composition or weight, this study demonstrates that a body composition focused obesity management program can be successful at promoting stages of change progression, improved attitude and self-efficacy, increased resistance training exercise and days spent exercising, for certain people.

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CHAPTER 1

INTRODUCTION

A. Statement of the Problem

Obesity is a significant public health concern with over 108 million adults (61%) obese or overweight (Satcher, Lee, Joyner, & McMillen, 1999; Wyatt, 2003). Obesity is associated with an increase in morbidity which includes type 2 diabetes (Albu & Raja-Khan, 2003; Bloomgarden, 2003; Despres, 1998; Zimmet, 2003), coronary heart disease (Anderson, Kendall, & Jenkins, 2003; Barton & Furrer, 2003; Manson, Willett, Stampfer, Colditz, Hunter, Hankinson et al., 1995), and cancer (Ballard-Barbash & Swanson, 1996; Bray, 2003; Giovannucci, Colditz, Stampfer, & Willett, 1996).

However, although the U.S. had been the leader in establishing physical activity for health promotion, 60% of the U.S. population is not regularly active, with 25% not active at all (Satcher et al., 1999). The Department of Health and Human Services (DHHS) report that 300,000 people die per year from diseases and health complications due to a sedentary lifestyle. DHHS also states that 117 billion dollars are spent annually as a result of diseases related to inactivity, such as obesity, type 2 diabetes and heart disease (Thompson, 2002). The correlation continues to exist between decreased physical activity and disease, including obesity (Thompson, 2002).

While most obesity treatment has focused on lowering caloric intake, along with improving exercise activity and behavioral changes such as counting calories, both health professionals and overweight or obese individuals continue to focus on absolute weight loss as a key outcome. Weight and low calorie focused treatments often result in loss of fat free mass leading to a decrease in resting metabolic rate (Bryner, Ullrich, Sauers,

Donley, Hornsby, Kolar et al., 1999; Marks & Rippe, 1996; Pasanisi, Contaldo, de Simone, & Mancini, 2001) causing weight loss and maintenance to be even more difficult. However, when resistance training or aerobic physical activity is incorporated, even without the loss of absolute weight, fat free mass is maintained or increased (Banz, Maher, Thompson, Bassett, Moore, Ashraf et al., 2003; Deschenes & Kraemer, 2002; Park, Park, Kwon, Kim, Yoon, & Park, 2003; Ross, Freeman, & Janssen, 2000; Tsutsumi, Don, Zaichkowsky, & Delizonna, 1997). Client understanding of resistance training mechanisms to increase muscle and decrease fat mass and how these changes in body composition affect health and metabolism may lead to an improvement in their obesity management. This is a varied approach from absolute weight loss intervention which often leads to a decrease in metabolism resulting from a loss of muscle mass making weight maintenance and continued overall fat loss more difficult. (Ross, Freeman et al., 2000; Tsutsumi et al., 1997).

B. Purpose of the Study

The purpose of the study was to determine if a body composition focused approach to obesity treatment results in a positive change in attitude regarding obesity treatment from a focus on absolute weight loss to a focus on body composition change. Secondly, this study examined if there was a change in attitude, followed by assessment of whether this change in attitude was accompanied by improved fat free mass and lowered fat mass, increased strength training behavior, a consistent progression through the stages of change up to the action stage, improved self-efficacy and higher outcome expectations.

C. Theoretical Framework

It is well established that exercise and activity play an important role in decreasing morbidity. However, unless individuals actually adopt and maintain an active lifestyle, emphasizing physical activity is pointless. Therefore, identification of underlying modes to increase and maintain activity is crucial, such as improving self-efficacy related to an exercise behavior and targeting individual's specific stage of change.

1. Description of the Social Cognitive Theory (SCT)

The *social cognitive theory* was intended to describe how cognitive and social influences affect behavior (Bandura, 1977; Bandura, 2001). It illustrates the continual reciprocal interaction between a person and their environment, thus determining behavior. As variables in the social cognitive theory, self-efficacy and outcome expectations influence behavior. Self-efficacy is defined as confidence to perform a behavior in a particular situation. Evidence has shown that in some instances, self-efficacy strongly predicts future health behavior, more so than past performance (Bandura, 1977; DiClemente, 1981). It is also a significant contributing factor to the choice, effort and persistence individuals elicit for any activity self-efficacy is a significant contributing factor to the choice, effort, and persistence individuals elicit for any activity (Bandura, 1997; McAuley & Blissmer, 2000). Outcome expectations, another variable in the social cognitive theory, are the beliefs that specific outcomes will be affected by personal action (Bandura, 1997). An individual may take into account various potential outcomes, comparing the possible benefits prior to beginning effort.

However, when long-term outcomes present a challenge or do not contain immediate benefit from the effort, self-efficacy becomes an important determining factor in choosing to change the specified behavior (AbuSabha & Achterberg, 1997).

2. Application of the Social Cognitive Theory to Health Behavior Change (SCT)

As part of the *social cognitive theory*, self-efficacy and outcome expectations play a powerful role in determining which active efforts individuals choose in adopting a health behavior and the resulting consequences. As an example, an individual involved in this study may have outcome expectations related to a decrease in body fat that is the result of adding resistance training to their exercise schedule. However, improving the individual's self-efficacy towards resistance training is important if the effort of resistance training is to be accomplished.

a. Self-Efficacy. Self-efficacy has been studied extensively in relation to physical activity (Marcus, 2000; Marcus, Selby, Niaura, & Rossi, 1992a; McAuley et al., 2000; Ryckman RM, 1982; Ryckman, 1982). Especially in the early stages of exercise adoption, but even into maintenance, self-efficacy directly affects health behaviors directed at choosing a physical activity (Marcus & Owen, 1992; McAuley et al., 2000). Self-efficacy is influenced by past performance, social modeling, physiological arousal, verbal or social persuasion and is considered the strongest influence on behavior (Bandura, 1997).

To summarize, as part of Bandura's *social cognitive theory*, self-efficacy is related to prediction and outcome of situational behaviors. Self-efficacy has also been integrated into the transtheoretical model often affecting movement between the stages of

change. In this study, self-efficacy, outcome expectations and stages of change were assessed in relation to a body composition focused obesity management intervention to measure whether the intervention improved each component as proposed.

b. Outcome Expectations. Outcome expectations, another variable in the *social cognitive theory*, are the beliefs that specific outcomes will be affected by personal action (Bandura, 1997). Self-efficacy and outcome expectations influence course of action in adopting a health behavior and the resulting consequences. Self-efficacy and outcome expectation instruments, specific to exercise and physical activity, exist and have been validated across various populations (Bernier, 1986; Clark, Abrams, Niaura, Eaton, & Rossi, 1991; Marcus, Selby et al., 1992a; McAuley, 1992; McAuley et al., 2000; McAuley, Lox, & Duncan, 1993; Sallis, Haskell, Fortman, Vranizan, Taylor, & Solomon, 1986). Bandura stated that individuals base the outcomes of a behavior on the ability to perform that behavior. Therefore, when choosing a behavior, individuals rely on self-efficacy directly affecting the outcomes produced by the chosen behavior (Bandura, 1997).

Although extensively studied in relation to exercise, self-efficacy and outcome expectations have not been addressed specific to resistance training activity and body composition focused obesity treatment. In order to adequately assess the self-efficacy changes that take place with relation to resistance training, an assessment instrument, specific to changes that take place in a body composition focused obesity management program, was needed. An assessment instrument was also needed for outcome expectations, as related to expected changes that take place when enrolled in a body composition focused obesity treatment. Adaptation of the existing instruments can help

in the exploration of a body composition focused obesity treatment and the effect on self-efficacy and outcome expectations.

3. Description of the Transtheoretical Model Stages of Change (TTM)

Based on the *transtheoretical model* (Prochaska & Velicer, 1997a; Prochaska & Velicer, 1997b), the construct of the stages of change describes the movement through five stages in a person's attempts to adopt and maintain a specific behavior. The *TTM* focuses on an individual's decision making towards actual behavior and intention to perform that behavior (Marcus, Pinto, Simkin, Audrain, & Taylor, 1994), and is designed to develop interventions targeting specific needs of an individual (Prochaska et al., 1997a; Prochaska et al., 1997b). The five stages are identified as: Precontemplation (not thinking about making change), Contemplation (thinking about making a change within six months), Preparation (actual making a small change), Action (engaging in the new behavior for 0-6 months), and Maintenance (continuation of the new behavior beyond 6 months) (Marcus, Pinto et al., 1994; Prochaska, Velicer, Rossi, Marcus, Fiore, Harlow et al., 1994). Regression can occur when individuals revert to an earlier stage. This is true of many health behavior changes. However, when related to exercise, only approximately 15% regress back to the precontemplation stage, while most individuals regress to the contemplation or preparation stage (Prochaska et al., 1997a; Prochaska et al., 1997b).

4. Application of the Transtheoretical Model Stage of Change to Exercise Behavior (TTM)

The *transtheoretical model* stages of change has been studied extensively in relation to exercise behavior across various populations (Bock, Marcus, Rossi, &

Redding, 1998; Cardinal, 1995; Marcus, Banspach, Lefebvre, Rossi, Carleton, & Abrams, 1992; Marcus, Pinto et al., 1994; Marcus & Simkin, 1994; Prochaska, Velicer et al., 1994; Riebe, Greene, Ruggiero, Stillwell, Blissmer, Nigg et al., 2003; Rodgers, Courneya, & Bayduza, 2001). Movement or stagnation throughout the stages of change is influenced in part by self-efficacy. Self-efficacy plays a strong role in the adoption of exercise with individuals in the precontemplation and maintenance stages showing the lowest and highest self-efficacy scores, respectively (Cardinal, 1997; Marcus & Owen, 1992; Marcus, Selby et al., 1992a). Therefore, increasing an individual's self-efficacy related to a specific exercise behavior would likely mediate, in part, the progression through stages.

There are limitations to the stages of change model. Prediction of movement through the stages of change from precontemplation to contemplation is not always based on the pros and cons of a particular behavior (Herzog, Abrams, Emmons, Linnan, & Shadel, 1999). In addition, intervention directed at a specific stage has not shown to be as effective in changing target behaviors as hypothesized (Quinlan & McCaul, 2000). Thus, caution must be used when interpreting movement between stages of change and when changing targeted behavior by focusing on specific stages of change.

Assessment of the stages of change has also been studied extensively in relation to exercise behavior across various populations (Bock et al., 1998; Cardinal, 1995; Marcus, Banspach et al., 1992; Marcus, Pinto et al., 1994; Marcus & Simkin, 1994; Prochaska, Velicer et al., 1994; Rodgers et al., 2001). However, instruments specific to resistance training have not been developed. Therefore, in order to assess the stages of change that occur when individuals are enrolled in a body composition focused obesity

treatment with emphasis on resistance training, it is important to incorporate reliable instruments. Because validity and reliability are high for many of the exercise stages of change assessment instruments (Cardinal, 1997; Marcus & Owen, 1992; McAuley et al., 1993), adaptation of those instruments were expected to yield valid and reliable instruments.

D. Research Questions

1. Is there a significant change or relationship among the following variables: a) attitudinal change from a focus on absolute weight loss to focus on body composition change, b) progression through the stages of change toward the action phase, c) increased self-efficacy related to strength training, d) positive outcome expectations reflecting body composition change, and e) increased strength training exercise behavior among participants in the *Total Wellness* obesity treatment program?

2. Do mean scores on scales of attitudinal change, self-efficacy, stages of change, outcome expectations, body composition change and weight differ for subjects receiving group support compared to subjects receiving group plus individual support?

E. Specific Aims

1. To test the effectiveness of a body composition focused obesity management intervention to lower body fat, and improve stage of change, self-efficacy, outcome expectations, attitude, and exercise behaviors in adult females, from baseline to 3-months.

2. To develop valid and reliable instruments to assess stage of change, self-efficacy, outcome expectations, attitude, and exercise behaviors specific to a body composition focused obesity management intervention.

CHAPTER 2

LITERATURE REVIEW

Based on results from the Third National Health and Nutrition Examination Survey, 63% of men 55% of women are considered overweight or obese (body mass index ≥25 kg/m2, obese BMI ≥30 kg/m2) (Must, 1999). As indicated by the Centers for Disease Control and Prevention, overweight and obesity rates in the United States rose from 12% in 1991 to 18.9% in 1999 (Mokdad, Serdula, Dietz, Bowman, Marks, & Koplan, 1999, 2000) and from 19.8% in 2000 to 20.9% in 2001 (Mokdad, 2003). While weight loss is sometimes accomplished in encouraging the obese to use weight-focused programs, often a significant amount of the weight lost is fat free mass (FFM) resulting in a lowered resting metabolic rate (RMR) (Deschenes et al., 2002; Marks et al., 1996). As a result, a decrease in RMR makes continued weight loss or maintenance difficult. However, maintaining FFM using resistance training has shown to maintain or improve RMR (Banz et al., 2003; Tsutsumi et al., 1997; Wilmore, 1996). By shifting the focus of obesity treatment away from losing pounds to improving body composition, consequent lowered fat mass and health gains, including behavioral and cognitive, may result. This literature review discusses health implications of body composition, along with the potential effects of behavioral and cognitive changes on body composition.

A. Definitions of Obesity

Obesity is defined as an excess of body fat with potential health impairments (McArdle, 1996; Must, 1999; Organization, 1998). There are many ways to determine an individual's body fat which are discussed below.

1. Body Fat Percentage

Body fat percentage, based on calculations from skin fold measurements, bioelectrical impedance analysis or hydrostatic weight, indicates the following classifications: 'fat' 21-24% male, 28-32% female; and 'obese' ≥25% male, ≥33% female (Nieman, 1995). People with high to moderate percent body fat show increased prevalence for coronary artery disease, hypertension, diabetes mellitus, cancer (Barton et al., 2003; Bray, 2003; Despres, 1998; Singh, Niaz, Beegom, Wander, Thakur, & Rissam, 1999) and insulin resistance (Albu et al., 2003; Anderson et al., 2003; Barton et al., 2003; Bray, 2003; Istfan, Plaisted, Bistrian, & Blackburn, 1992).

2. Body Mass Index (BMI)

The National Institutes of Health (1998) and the World Health Organization (1998) define overweight as a BMI of 25-29.9, and obesity as a BMI ≥ 30. BMI is calculated as weight in kilograms divided by the square of the height (kg/m^2).

Body mass index has often been the form of measurement used to define overweight and obesity due to ease and simplicity of measurement. However, BMI does not account for percent body fat and is a direct calculation based on height and weight only. Because BMI does not account for body composition, namely body fat percentage (McArdle, 1996; Piers, Soares, Frandsen, & O'Dea, 2000), it has been suggested that body composition be used as a health indicator in place of BMI (Allison, Faith, Heo, & Kotler, 1997; Segal, Dunaif, Gutin, Albu, Nyman, & Pi-Sunyer, 1987). Even so, BMI does show strong correlation, although not perfect, to body fat percentage (r= .58-.82) (Leaf, Kobashigawa, Gleeson, & Laks, 1997; Smalley, Knerr, Kendrick, Colliver, & Owen, 1990). However, when compared to body fat, BMI misclassified individuals as

healthy more often (Ohno, Nishisaka, & Ikeda, 1998). Because of the misclassification of the overweight or obese individual as normal, it has been suggested that a fat mass based classification system be used in place of BMI (Hortobagyi, Israel, & O'Brien, 1994).

Similar to body fat percentage, body mass index is associated with increased type 2 diabetes (Anderson et al., 2003; Despres, 1998) coronary heart disease (Barton et al., 2003; Manson et al., 1995) and cancer, especially colon and endometrial (Bray, 2003; Giovannucci et al., 1996; Lee, 1992).

In summary, both percent body fat and body mass index showed increased incidence for morbidity related to cancer, coronary artery disease, diabetes mellitus and hypertension. However, BMI often misclassifies overweight or obese individuals as healthy when compared to body fat percent, leading to a false negative diagnosis. Because percent body fat has shown to correctly identify the obese individual based on actual measurement of body fat, this form of measurement should be used to classify participants seeking obesity treatment.

B. Morbidity Associated With Obesity and Lack of Physical Activity

Obesity is associated with many negative health impairments relating to inactivity. The U.S. Surgeon General indicated that inactivity increased the risk for all cause mortality and morbidity and coronary heart disease (Satcher et al., 1999). However, 60% of the U.S. population did not meet the minimal standards for physical activity of accumulation of 30 minutes of physical activity on at least 5 days per week, and 25% were not active at all (Satcher et al., 1999). Obesity, in the form of excess body fat, is also shown to increase the risk for mortality in males (Baik, Ascherio, Rimm,

Giovannucci, Spiegelman, Stampfer et al., 2000; Wyatt, 2003) and females (Manson et al., 1995; Wyatt, 2003). The combination of these factors, increased risk for morbidity and mortality, makes the assessment of a program that addresses physical activity and excess body fat, and not just weight loss, a key area in obesity management. Physical inactivity and resulting obesity have further health risks, which include the following:

1. *Type 2 Diabetes Mellitus*

An estimated 150 million adults worldwide have type 2 diabetes with a projected increase to 225 million by the year 2010 (Zimmet, 2003). Abdominal adiposity and BMI above 27 are directly associated with increased type 2 diabetes morbidity in men and women (Despres, 1998; Kaye, Folsom, Sprafka, Prineas, & Wallace, 1991; Satcher et al., 1999; Thompson, 2002). A BMI greater than 40 has the highest prevalence ratios of morbidity for type 2 diabetes for both men and women (PR=18.1 and 12.9, respectively) (Must, 1999).

2. *Coronary Heart Disease*

Obesity affects coronary heart disease (CHD) mainly by increasing health risk factors such as diabetes mellitus, hyperlipidemia, hypertension and decreased high-density lipoprotein (Bray, 2003; Cleeman & Lenfant, 1998). The Nurses' Health Study showed women with a BMI >32 had a higher relative risk of cardiovascular disease (RR= 4.1) when compared to lean women with a BMI <19 (Manson et al., 1995). Results from the Framingham Study (Garrison, 1985) support the connection between overweight and atherosclerosis, leading to CHD in men and women, and indicated that CHD can be lowered through a decrease in body fat (Kannel, 1991).

3. *Cancer*

Certain types of cancer have shown direct relation to increased weight, body fat and BMI. Male and female colon cancer (Giovannucci et al., 1996; Lee, 1992), and endometrial and postmenopausal breast cancer (Huang, 1997), show a positive relationship with weight, body fat and BMI greater than 29 (Ballard-Barbash et al., 1996).

To summarize, obese individuals, as indicated by a BMI $\geq$30 or body fat percentage $\geq$25 for males and $\geq$33 for females, showed increased risk for morbidity for various diseases including type 2 diabetes (Barton et al., 2003; Bray, 2003; Despres, 1998), coronary heart disease (Barton et al., 2003; Bray, 2003; Manson et al., 1995) and certain forms of cancer (Ballard-Barbash et al., 1996; Bray, 2003; Giovannucci et al., 1996). While inactivity has shown an increased risk for all cause morbidity and coronary heart disease, 60% of the U.S. population do not meet physical activity standards (Satcher et al., 1999). An obesity treatment program targeted at reducing body fat and increasing physical activity appears key in reducing mortality related to obesity and inactivity.

C. Anthropomorphic Assessments

Anthropomorphic measurements, assessment of size, weight, and proportions of the human body, can be used to determine where the subject is in relation to body fat, health status and achieving their obesity treatment goal (Nieman, 1995). Anthropometric measurements have also been indicated as the most appropriate body composition instrument for population surveys (Jensen, 1992). Many devices and procedures exist to determine these measurements. However, when working with the obese individual, particular tools are needed due to a larger amount of tissue and adiposity (Gray, Bray,

Bauer, Kaplan, Gemayel, Wood et al., 1990). Skin fold measurements are often used in clinical and population studies due to the accuracy and low cost (Brodie, 1988a, 1988b). However, when used with the obese individual, body fat is often underestimated when compared to hydrostatic measurements (Gray et al., 1990). Body mass index is simple and noninvasive, but only takes into consideration height and weight and may misclassify individuals (Smalley et al., 1990). Electrical impedance is also used often due to being noninvasive and portable. When used with the obese individual, electrical impedance is considered reliable (Hainer, Kunesova, Parizkova, Stich, Horejs, & Muller, 1995; Jebb, Cole, Doman, Murgatroyd, & Prentice, 2000).

1. Skin Fold Measurement

This type of anthropometric measurement, designed to measure percent body fat, requires reliable calipers placed at various anatomical sites. In particular, the *Lange* and *Harpenden* skin fold calipers are the recommended instruments especially when conducting population studies (Gruber, Pollock, Graves, Colvin, & Braith, 1990) although the *Lange* calipers have been used to develop many body fat prediction equations (Nieman, 1995). Skin fold measurements also requires intra- and inter-individual reliability. The 3-and 7-site skin fold measuring are rapid, inexpensive and have shown reasonable validity within 3-4% for 70% of the normal population (Brodie, 1988a; Jackson & Pollack, 1985). However, when assessing the obese individual with skin fold calipers, body fat is often underestimated due to the large amount of tissue placed within the calipers (Gray et al., 1990) and the increase of internal adiposity accompanied by obesity that is not measured with skin fold calipers (Brodie, 1988a). Although only a small difference, when compared to skin fold measurements of non-

obese women (r=0.61), obese women had slightly lower correlation of body fat (r=0.58) when hydrostatic measurement was used as the criterion measure (Heyward, Cook, Hicks, Jenkins, Quatrochi, & Wilson, 1992).

When compared to hydrostatic measurements, often considered the criterion method due to the ability to measure internal adiposity, skin fold measurements showed a non-significant difference in means of percent body fat (p= 0.53) (Brodie, Eston, Kreitzman, & Coxon, 1989). The equipment needed for hydrostatic measurements is expensive and individuals must be confident of the water, making use of skin fold measurements more convenient (Brodie et al., 1989).

When used in a normal population, skin folds are reasonably accurate and easy to use (Brodie, 1988a). However, when used with the obese population, underestimation of body fat can occur (Gray et al., 1990; Heyward et al., 1992).

2. Body Mass Index

Body mass index (BMI) is a simple, noninvasive method for measuring adiposity. It is easily calculated using weight (kg) divided by height (m^2). However, because BMI takes into account only height and weight and does not distinguish body composition of fat or muscle, misclassification of individuals occurs. Of special importance is the failure to identify individuals who indicate 'healthy' on the BMI scale but are actually 'over-fat' or 'obese' in relation to body fat content. When compared with hydrostatic measurements body fat standards, BMI showed lowered sensitivity in both males (54.5%) and females (26.9%) to classify participants as obese (Hortobagyi et al., 1994). And when compared against bioelectrical impedance, BMI misclassified 7.3% participants as

healthy when the percent body fat was >25% and 7.6% of the participants when the body fat percent was >30 (Ohno et al., 1998).

Recently, research has been conducted to connect BMI guidelines with predicted body fat percentage (Gallagher, Heymsfield, Heo, Jebb, Murgatroyd, & Sakamoto, 2000). In assessing 1,626 subjects from various ethnic groups (Caucasian, African American and Asian), the relationship was shown to be quite high, although not perfect, between BMI and body fat (r= 0.74-0.92).

Because BMI does not account for variation in body composition, namely muscle and fat mass, it can misclassify individuals. Although it has shown strong correlation to percent body fat, measurement of body composition using hydrostatic or skin fold measurement is more sensitive in identifying the obese individual.

3. Electrical Impedance

Bioelectrical impedance analysis (BIA) involves the use of low amperage current through the skin of the feet and is used to measure percent body fat and fat free mass. BIA is noninvasive and portable and easy to use by both examiner and subject. It is reliable among normal and obese populations (Hainer et al., 1995; Jebb et al., 2000; Lawlor, 1985). Validity has also shown to be strong with both male and female subjects (Lawlor, 1985) when compared to hydrostatic weighing. When compared with hydrostatic measurements, BIA showed stronger correlation (r=0.78, p=0.001) in measuring percent body fat in obese and non-obese women (Utter, Nieman, Ward, & Butterworth, 1999). Recently, the *Tanita Body Fat Analyzer* has shown strong correlations when compared to skin fold measurements with a mean bias of 0.3kg (Jebb et al., 2000). Comparison between a direct measurement of body fat, dual energy x-ray

absoptiometry, and skin fold versus BIA, showed that BIA ($r=0.86$, $p=<0.001$) assessed changes in body fat more accurately than skin fold measurements ($r=0.73$, $p<0.001$) (Punyanitya, Nunez, Rubiano, & Heymsfield, 1999).

Electrical impedance shows strong correlation to hydrostatic and dual energy x-ray absoptiometry measurements in determining percent body fat. It shows ease of use by both examiner and subject and is portable making BIA is valuable and accurate tool in assessing the obese and non-obese persons.

In summary, when assessing the non-obese person, skin fold measurements are accurate in measuring percent body fat. However, when used with the obese individual, skin fold measurements tend to underestimate body fat percent. Body mass index, used widely in population studies, only measures height and weight and does not take into consideration body composition. Although it has shown high correlation with body fat, BMI often misclassifies individuals as healthy when body fat percent would classify the individuals as overweight or obese. Because of the false classification, BMI must be used with caution when classifying individuals. "The most accurate assessment of obesity is the body fat content" (Atkinson, 1993, p. 678). Electrical impedance has shown strong correlation with both hydrostatic and dual energy x-ray absoptiometry measurements of body fat percent. It is easy to use by the participant and examiner and provides accurate measurement for classification of the obese individual supporting BIA as a good choice for body fat measurement in obesity research.

D. Weight Loss

In 1998 as part of the Behavioral Risk Factor Surveillance System (BRFSS), it was found that 53.8% of the United States population was overweight (BMI 25-29) or

obese (BMI ≥30). Of these individuals, 50.4% reported trying to lose weight (Cook, Owen, Bender, Clark, Davis, Leff et al., 2000). Frequently practiced weight loss efforts include weighing oneself regularly, consuming diet soft drinks, counting calories, eating less, participating in organized weight loss programs (Levy, 1993; Stephenson, 1987; Williamson, 1992), increasing physical activity or a combination of several efforts (Cook et al., 2000; Horm, 1993)

Contributing to the cycle of continued unsuccessful efforts to lose weight and maintain weight loss is the fact that weight and low calorie focused treatments often result in a loss of fat free mass. Up to 40% of the weight lost is often composed of FFM with a consequential decrease in the resting metabolic rate and lowered energy expenditure (Marks et al., 1996). However, when focus is placed in increasing physical activity in the form of resistance training, FFM is spared while body fat is lost (Banz et al., 2003; Tsutsumi et al., 1997; Wilmore, 1996).

1. Treatment and Outcome

There is support for emphasis on measures such as body size and body fat, instead of the traditional focus on absolute weight lost, as a more accurate evaluation for a successful obesity treatment program (Atkinson, 1993; Miller, 1999). Researchers, using a randomized, controlled study design, found that an improvement in body composition, rather than loss of absolute weight, lead to greater obesity related health improvements such as hypertension, hyperlidiemia and hyperglycemia (Sayler, Goldstein, Roback, & Atkinson, 1994).

To support the need for a successful obesity treatment program (Senekal, 1999), a shift was proposed from the traditional unidimensional weight loss program focusing on

absolute weight, to a multidimensional program that focuses on multiple aspects of obesity related issues including prevention, treatment and management. The author has proposed that weight management include education on environmental influences, intrapersonal characteristics, formulation of reasonable weight goals and prevention of weight gain relapse. However, research applying this paradigm shift and reporting outcomes is not available in literature. And, while this incorporates a more rounded approach to overweight management, the focus is still be on controlling absolute weight. This may not be the best means of managing obesity when considering body composition.

2. Behavioral Therapy and Exercise

Behavior therapy for obesity including nutrition counseling, exercise therapy, cognitive restructuring and stimulus control has received considerable attention. When combined with exercise, behavioral therapy has shown to be effective in weight loss and maintenance (Di Loreto, Fanelli, Lucidi, Murdolo, De Cicco, Parlanti et al., 2003; Johnson, 1979). Safer (Safer, 1991) showed similar results of weight loss and maintenance when compared to traditional weight loss programs, although the behavioral group received a lowered caloric diet. Other researchers (Sbrocco, Nedegaard, Stone, & Lewis, 1999), using a randomized design comparing a traditional weight focused behavior therapy group and an exercise plus traditional weight focused behavior therapy group in women, showed that the traditional treatment group lost more weight initially, although the exercise group continued to lose weight even after treatment during the follow-up phase.

Recent research indicates that aerobic exercise (walking, jogging) without absolute weight loss, conducted 45 to 60 minutes per day, compared to low caloric intake treatment leads to a reduction in body fat especially visceral fat in men (Ross, Dagnone, Jones, Paddags, Hudson, & Janssen, 2000; Ross, Freeman et al., 2000). After three months of intervention, the average reduction of total fat was 1.3 kg greater ($p=0.03$) in the exercise-induced weight loss group than in the diet-induced weight loss group. Abdominal fat, measured using waist circumference, also decreased more significantly by 0.5 cm in the exercise induced weight loss group ($p<0.001$). Skeletal muscle mass, which decreased in the diet induced group, remained unchanged in the exercise group ($p>0.10$). This evidence suggests that physical activity alone can lead to a reduction in fat mass and may prove a successful intervention for body composition change even if there is no loss of weight. Aerobic activity has also shown a connection to weight maintenance and weight gain prevention. Based on data from the Multiple Risk Factor Intervention Trail (MRFIT), it was found that those individuals who increased physical activity during or following the trial were least likely to re-gain weight compared to those who did not adopt or increase physical activity (Blair, 1993).

While aerobic exercise with behavioral therapy has been shown to have positive changes in both body composition and weight maintenance, a program combining a focus on resistance training to improve body composition and behavioral therapy among the overweight and obese population has not yet been addressed in literature.

3. Resistance Training

Accumulation of 30 minutes or more of moderate intensity physical activity, including resistance training, on 5 or more days of the week or 20 to 60 minutes of

vigorous intensity exercise on at least 3 days of the week is recommended for adults (Pate, Pratt, & Blair, 1995; Thompson, 2002). The Department of Health and Human Services reports that over 60% of American adults are not meeting these standards while 25% of American adults are not active at all (Satcher et al., 1999). However, adoption of physical activity can be influenced by intensity level, improving self-efficacy related to specific exercise behaviors and targeting individuals at specific stage of change when working to implement exercise behavior. Physical activity that is low to moderate in intensity is adopted and maintained more often (Clark, Stump, & Damush, 2003; Lee, Jensen, Oberman, Fletcher, Fletcher, & Raczynski, 1996; Sallis et al., 1986). Although not yet examined with middle-aged adults, older adults who took part in a program structured around resistance training showed improvements in overall muscle gain, loss of body fat and an increase in self-efficacy to perform physical activity (Tsutsumi et al., 1997).

The need to maintain fat free mass during weight loss is evident based on the positive association between fat free mass (FFM) and resting metabolic rate (RMR) (Deschenes et al., 2002; Marks et al., 1996). When used alone or combined with a low caloric intake treatment, resistance training prevents the decline in FFM and muscular power and improves body composition. This is evidenced by comparison of three groups: weight loss induced by decreased caloric intake alone, weight loss induced by decreased caloric intake combined with aerobic exercise, and weight loss by decreased caloric intake combined with aerobic and strength training exercise (Kraemer, Volek, Clark, Gordon, Puhl, Koziris et al., 1999). At the end of the 12-week treatment, all three groups showed significant loss of body weight (p=.05). However, the strength training

group lost significantly more of the body weight as fat mass (97%) than did the decreased calorie group or the decreased calorie plus aerobic group (69% and 78% respectively, p=.05). Another randomized controlled study showed that the group participating in strength training, versus aerobic and reduced calorie only groups, lost significantly less fat free mass (p=.05) although no significant differences were found with weight lost between groups (Geliebter, Maher, Gerace, Gutin, Heymsfield, & Hashim, 1997). Additional evidence has shown that resistance training has the most significant effect on increasing FFM and decreasing fat mass leading to possible improvements in RMR (Saris, 1995; Vortuba, 2000). Resistance training is also effective for reduction and maintenance of body fat (Banz et al., 2003; Park et al., 2003; Saris, 1995; Tsutsumi et al., 1997).

While resistance training has been shown to improve body composition during obesity treatment, research is lacking in the area of assessing an obesity treatment program that focuses specifically on body composition changes through resistance training. Assessing changes in self-efficacy and stages of change related to resistance training or an approach that focuses on body composition change and not absolute weight loss has not been published to date. In addition, no research has addressed whether an approach that focuses on body composition instead of weight loss leads to an attitudinal change regarding obesity management and higher outcome expectations related to improvement in body composition for obesity management.

4. Individual and Group Support

The issue of the relative effectiveness of group versus individual support during weight loss has been addressed. Most studies indicated no significant differences

between the two types of support, although a difference between groups was found when maintenance of weight loss was examined (Adams, Grady, Wolk, & Mukaida, 1986; Balle & Almdal, 1996; Wadden, Berkowitz, Vogt, Steen, Stunkard, & Foster, 1997). In a study involving male and female participants, male participants who received individual support showed significantly more weight loss maintained five years post-treatment than did the group counseled male participants (12.9 kg and 3.0 kg, respectively) (Hakala, Karvetti, & Ronnemaa, 1993). No significant differences were noted for the female participants.

Several important factors have been suggested as a result of assessing group and individual therapy with weight loss. The first is that group sessions offer more social support meeting the need for heightened social interaction in some individuals (Hayaki & Brownell, 1996; Moe, Elliot, Goldberg, Kuehl, Stevens, Breger et al., 2002). Also, because group counseling can serve a greater number of individuals at one session than individual counseling, group sessions are seen as more cost effective in the health care setting (Hayaki et al., 1996).

While results from most weight loss focused studies have shown no significant differences between individual and group counseling, valuable information has been gleaned. Of special importance are the possible differences between men and women and how individuals respond to the different type of session along with cost of group versus individual counseling sessions and the social support provided more by group sessions. While these results are valuable especially when developing an obesity treatment program, no studies have addressed the differences between group and individual treatment when the focus is on body composition change.

E. Conclusion

Obesity management is important due to the increased risk for morbidity that accompanies overweight and over fat. Research is lacking in approach to the design of a weight loss program that would incorporate change in body fat and muscle composition and exclude focus on absolute weight change. However, limited behavioral research does suggest that even when absolute weight is not lost, physical activity, especially resistance training to increase muscle mass, can promote body fat loss (Banz et al., 2003; Park et al., 2003; Ross, Dagnone et al., 2000). However, while studies have addressed differences in individual and group support throughout weight loss, differences between individual and group support during a body composition focused obesity treatment have not been studied. Research indicates that males and females respond differently to each type of support (Adams et al., 1986; Hakala et al., 1993). Also, cost effectiveness and social support through group sessions have been noted (Hayaki et al., 1996; Moe et al., 2002).

This study was proposed to identify possible mechanisms that a body composition focused obesity treatment program has on reducing obesity by improving body composition as well as the effect on self-efficacy and movement through the stages of change related to resistance training, and changes in outcome expectation and attitude related to a decrease in body fat and increase in fat free mass. The design of instruments specifically tailored toward assessing self-efficacy, outcome expectations, stage of change and attitudinal change related to body composition has begun to set the stage for further exploration into the area of body composition focused obesity management. Changing an individual's perception of health to body composition instead of absolute

weight and assessing behavioral and cognitive changes that take place may provide a framework for successful obesity treatment.

CHAPTER 3

METHOD

A. Design

The current investigation was an experimental pretest-posttest design with random assignment to: 1) support group (SG), or 2) support group plus individual appointments (SG + I), over five cohorts, in a body composition focused obesity management program.

B. Study Sample

The sample size was estimated to be 64 subjects per group based on analysis of variance, with a medium effect size (.50), power at .80 and alpha of .05 (Cohen, 1992). Subjects were selected from Beaver Medical Group clients who enrolled in the *Total Wellness* obesity treatment program from July, 2001 to February, 2002. Subjects were included if they:

1) Were $\geq$ 21 years;

2) Had overweight or obesity status, based on physician diagnosis and/or body composition measurement (Nieman, 1995);

3) Had no current participation in any other weight loss treatment, medical, dietary or behavioral within the past one month;

4) Completed PAR-Q form with no answers indicating activity restriction based on health status unless referred by physician, and

5) Signed an informed consent.

One hundred fourteen male and female subjects consented and met criteria to participate in this study. However, after a 58% dropout and non-compliance to study

protocol, and exclusion of the remaining two males for generalization only to a female population, the study population consisted of 48 women (42% of enrolled subjects), 24 per treatment group.

C. Procedures

Recruitment of subjects took place July 1, 2001 through February 28, 2002 at Beaver Medical Group, Redlands, California and medical clinics affiliated with Beaver Medical Group. A letter discussing the research project (refer to Appendix C) was sent to all referring Beaver Medical Physicians and Personnel.

Once physician referrals were received through the Patient Education Department, the Primary Investigator (PI) (refer to Appendix A) proceeded with requirements for this assessment study by contacting each potential participant by telephone (refer to Appendix D) to inform them of the study, their responsibilities and time commitment required along with initial screening based on inclusion criteria. After verbal agreement by the potential participant to enter the study, an appointment was scheduled by the PI to obtain informed consent and baseline pre-treatment data, thus signifying entrance into the study.

Based on requirements for this assessment study, randomization of subjects to the two treatment groups, *Total Wellness* Support Group only (SG) or *Total Wellness* Support Group plus individual appointments (SG + I), took place after subjects agreed to enter the study and an appointment for pre-treatment testing had been scheduled.

D. Intervention

The *Total Wellness* (TW) *Class* is a year-around obesity management program, taught by a Preventive Care Specialist (PCS), that takes place for two hours, two Mondays per month, in a group setting at Beaver Medical Group, Redlands, California.

It is designed to be a one-time class that addresses a focus on body composition change through resistance training and increased physical activity, improved nutrition, balancing caloric intake with basal metabolic rate and decreasing focus on absolute weight loss. Follow-up and support are provided by the *Total Wellness* Support Group class (TWSG), also taught by the PCS and, on occasion, DrPH students from Loma Linda University School of Public Health. The *Total Wellness* Support Group meets twice per month, one hour per session, and addresses areas discussed in the *Total Wellness* class such as nutrition, exercise intensity, increasing muscle mass, and resistance training and physical activity. Individual appointments with the PCS or a DrPH intern can also provide support and are used in conjunction with the TWSG as needed. The *Total Wellness* class, *Total Wellness* Support Group classes and individual appointments are all part of the standard of care for Beaver Medical Group *Total Wellness* program patients.

In this study, all subjects attended one *Total Wellness* class during month 1 of treatment, following the *Total Wellness* program standard of care. Following random assignment, half of the subjects were placed in the *Total Wellness* Support Group only group (SG) and half in the *Total Wellness* Support Group plus individual appointment group (SG + I). SG subjects attended one TWSG class during months 2 and 3 of treatment. SG + I subjects also attended one TWSG class during months 2 and 3 of treatment, and were individually scheduled with the PCS or Primary Investigator for two separate 30-minute appointments to meet once per month during months 2 and 3 of treatment.

Following the study treatment, all study subjects were given the opportunity to receive additional class and individual support through the *Total Wellness* class, *Total*

Wellness Support Group classes, and individual appointments, included in the *Total Wellness* program standard of care.

E. Dependent Variables and Measures

The dependent variables assessed in this study at baseline and 3-months post-treatment were as follows: 1) body composition, 2) weight, 3) change in attitude, assessed to determine the progression from a focus on absolute weight loss to a focus on body composition change, 4) self-efficacy, 5) outcome expectations, 6) stage of change, 7) exercise behavior(s), and 8) duration of exercise behavior(s). Body composition and weight were chosen because previous research suggests that success of an obesity management program be partially based on body fat loss and fat free mass gain in addition to weight loss (Allison et al., 1997; Segal et al., 1987) and due to the primary focus of this study. Assessment of body composition, weight, exercise behaviors and exercise duration were already part of the *Total Wellness* program standard of care. Assessment of attitude change, self-efficacy, outcome expectations, and stage of change were based on requirement for this study only.

1. Body Fat

a. Bioelectrical Impedance Analysis. Hydrostatic weight, used to estimate body density, is considered the criterion method due to the high precision and reliability especially when residual volume can be calculated accurately. However, because this method is expensive, body composition was assessed using the *Tanita* bioelectrical impedance analysis (BIA) body fat scale, model TBF300. BIA is a non-invasive quick way to measure body composition in a practice setting. It is reliable instrument in the obese and non-obese individual when compared to hydrostatic measurement ($r=0.78$,

p=0.001) (Utter et al., 1999) and dual x-ray absorptiometry (r=0.86, p=<0.001) (Punyanitya et al., 1999), with strong correlations for measurements taken hours to days apart (Lawlor, 1985; Lukaski, 1984; Lukaski, 1985). Accuracy in bioimpedance measurements depends largely on pre-assessment subject compliance with the following: avoid moderate or vigorous physical activity within 12 hours; void completely; abstain from alcohol consumption for 48 hours; and ingest no diuretic agents, including caffeine, unless directed by physician (Balady, Berra, L.A., Gordon, Mahler, Myers et al., 2000). Bioelectrical impedance assessment was already a part of the *Total Wellness* program standard of care.

b. Skin Fold Measurements. To help improve accuracy of body composition measurements, 7-site skin-fold measurements was also taken using *Lange* calipers. Skin fold measuring is rapid, inexpensive and has shown reasonable validity within 3-4% for 70% of the normal population (Brodie, 1988a, 1988b). Skin fold measurements have strong correlations (r=0.70 to 0.90) when compared to hydrostatic weight (Balady et al., 2000). Predicting accuracy of percent body fat from skin folds is $\pm$ 3.5% (Heyword VH, 1996). Measurements were made by the PI and/or PCS and followed American College of Sports Medicine guidelines which state: "all measurements to be made on the right side of the body; caliper placed 1cm away from the thumb and forefinger, perpendicular to the skin fold and halfway between the crest and base of the fold; pinch should be maintained while reading the caliper; wait 1-2 seconds before reading caliper; take duplicate measures at each site and retest if duplicate measurements are not within 1-2mm; rotate through measurement sites or allow time for skin to regain normal texture and thickness" (Balady et al., 2000, p. 65). Anatomical locations for the 7-site skin fold

measurements for males and females are: chest, midaxillary, triceps, subscapular, abdomen, suprailiac, and thigh. Calculation was based on the Jackson-Pollock skin fold equation (Jackson et al., 1985). Skin fold measurements were already a part of the *Total Wellness* program standard of care.

2. Attitude Toward a Body Composition-Focused Obesity Management Program

To assess subject's attitude change that is hypothesized to take place during the body composition focused treatment program, a questionnaire was developed using a 5-point Likert-type scale. Items were specific to weight, body composition and dietary intake change as discussed in the Total Wellness program with 1 indicating "strongly disagree" and 5 indicating "strongly agree". Positively and negatively worded items were arranged randomly to reduce response bias. Prior to this study no such scale existed, so development was based on specific attitudes targeted as part of the treatment. Items reflect specific attitudes affected by the body composition focused program. Internal reliability based on Cronbach's alphas for the pre and post-treatment questionnaires were 0.50 and 0.49, respectively. Attitude change was assessed at baseline and 3-months post-treatment. (Refer to Appendix F.)

3. Self-Efficacy for Resistance Training

As part of the *social cognitive theory*, self-efficacy is related to prediction and outcome of situational behaviors (McAuley et al., 2000; McAuley et al., 1993; Sallis et al., 1986). Self-efficacy has also been integrated in to the *transtheoretical model* and is hypothesized to influence movement between the stages of change (Marcus, Selby et al., 1992a). Specific to this study, self-efficacy was defined as the subject's belief in their

abilities to implement muscle-building exercise (resistance training) as required for improvement in body composition.

Self-efficacy was assessed using a Likert-type scale following general guidelines for measuring self-efficacy (Bandura, 1977; Bandura, 1997). Measures targeted specific behaviors related to strength training. The assessment of self-efficacy was developed using three existing exercise self-efficacy scales: the 5-item *Exercise Self-Efficacy Scale* (Marcus, Selby, Niaura, & Rossi, 1992b) with a Cronbach's alpha range of 0.773 to 0.869; a 3-population 5-item exercise self-efficacy scale (Rodgers et al., 2001) with Cronbach's alpha of 0.76; and *McAuley's 13-item Exercise Self-Efficacy Questionnaire* (McAuley, 1992) with a Cronbach's alpha of 0.88.

The instrument, developed from the above three scales, measured self-efficacy using a 5-point Likert-type scale with 1 indicating low self-efficacy and 5 indicating high self-efficacy. The nine questions were designed to address elements affecting participation in resistance training activity including weather, mood, schedule change and convenience. Internal reliability was good based on Cronbach's alphas of .86 and .91 for pre and post-treatment questionnaires, respectively. (Refer to Appendix F.)

4. Outcome Expectations

Outcome expectations addressed subject's expectation of body composition and fitness related outcomes. The instrument examined the extent the participants expected the body composition focused program to: 1) increase fat free mass, 2) decrease fat mass, 3) increase strength training behavior(s), and 4) decrease weight. Because no scale existed prior to this study, to assess these items, development reflected specific outcomes related to the body composition focused program and followed guidelines outlined by

Bandura on how to assess outcome expectation within the social cognitive theory (Bandura, 1997, 2001).

Outcome expectations were assessed at baseline and post-treatment and were measured using a 5-point Likert-type scale with 1 indicating "strongly disagree" and 5 indicating "strongly agree". The eight items addressed weight and body composition change, exercise type, and dietary intake. Positively and negatively worded items were arranged randomly to reduce response bias. After reverse scoring of items three, four and eight and deleting item three, reliability increased to 0.61 and 0.65 respectively. (Refer to Appendix F.)

5. *Stages of Change*

The construct of the stages of change, based on the *transtheoretical model* (Prochaska et al., 1997a; Prochaska et al., 1997b), identifies an individual's movement through five stages in attempt to adopt and maintain a specific behavior. The five stages are identified as: Precontemplation, Contemplation, Preparation, Action and Maintenance. Focus is on actual behavior and intention to perform behavior (Marcus, Pinto et al., 1994).

The stages of change were assessed using a Likert-type scale following general guidelines for measuring the five stages of change (Prochaska, Norcross, & DiClemente, 1994; Prochaska et al., 1997a; Prochaska et al., 1997b) and was specific to resistance training. Construction of the stages of change scale were developed using two existing scales: the *Stage of Exercise Adoption Scale* (Marcus, Pinto et al., 1994; Marcus & Simkin, 1994) with a Kappa index reliability of 0.78; and the *Exercise Stages of Change Short Form* scale (Marcus, Selby et al., 1992a) with a Kappa index reliability of 0.78.

The instrument was developed using the existing scales mentioned above and measured stage of change using five questions related to current participation in resistance training activity. Questions were arranged to assess precontemplation, contemplation, preparation, action or maintenance phase. (Refer to Appendix F.)

6. *Exercise Behaviors*

To assess the type of exercise behavior(s) practiced, which included aerobic, resistance and leisure, and duration of exercise behavior(s), each participant completed a questionnaire which addressed the exercise behavior(s) practiced, and average length of time based on minutes per day within the last 7 days. (Refer to Appendix F.)

F. Data Collection

Approval from the Institutional Review Board of Loma Linda University, based on submission of the proposal following approval of the proposal by the DrPH Sub-Committee, was received July 28, 2001. Approval from the Beaver Medical Group Review Board, based on approval from the Loma Linda University Institutional Review Board, was received July 30, 2001.

Pre-treatment baseline collection of data began July 30, 2001 and proceeded through February 4, 2002. Prior to beginning a treatment program, subjects met individually with the PI, at Beaver Medical Group in Redlands, outlining the requirements of the study, explanation and administration of informed consent, administration of the baseline questionnaires, body composition and weight measurements and exercise behavior assessment. Subjects were given a participation packet that included a copy of their signed consent form (refer to Appendix E) along with

the California Subject's Bill of Rights, schedule of required *Total Wellness* class, *Total Wellness Support Groups* and individual appointment dates.

Total Wellness classes took place the first and second Mondays of August, 2001 through February, 2002, as part of the current *Total Wellness* program standard of care. Participants were required to attend one 2-hour *Total Wellness* class, either in the morning of the first Monday or the evening of the second Monday during month 1 of intervention. *Total Wellness* support group classes took place September, 2001 through April, 2002, on the third and fourth Mondays of each of these months. Participants were required to attend one 1-hour *Total Wellness* support group classes, once during months 2 and 3 of intervention.

Post-treatment data collection began November 1, 2001 and proceeded through May 31, 2002 based on a 3-month treatment period. Subjects met individually with the PI for the administration of the post-treatment questionnaires, body composition and weight measurements and exercise behavior assessment. Compensation for participation was given at this time.

The post-hoc one-year follow-up study, added to the study design after completion of the 3-month follow-up, began 12-months following subject's first *Total Wellness* class and was surveyed via telephone once verbal consent had been obtained (Refer to Appendix C). Twenty-one participants from the original 48 subjects (44%) completed the one-year follow-up assessments.

G. Data Analysis

The Principal Investigator, using software SPSS Version 10.0, performed data entry and statistical analysis on a personal desktop computer.

Independent T-tests for two groups were used to assess differences between SG and SG+I groups on all continuous level variables at post-treatment. ANOVA controlling for baseline values, and chi square analysis for categorical variables, were performed to examine interactions and associations, respectively, between self-efficacy, stage of change, exercise type, and body fat. In addition, paired T-tests were used to assess pre- and post-test differences among dependent variables across groups. Pearson's chi square correlations were used to check for linear associations among self-efficacy, stage of change, outcome expectation and exercise behaviors at 3-month post-assessment across groups.

Cronbach's alpha was used to test internal reliability of each item included in the attitudinal change, self-efficacy, stage of change and outcome expectation assessment tools.

CHAPTER 4

PUBLISHABLE PAPER

Title: Assessment of a Body Composition Approach to Obesity Treatment in Adult Females

Authors: Beverly D. Hall, RN, Helen Hopp Marshak, Ph.D., Ernie Medina, DrPH, Christine M. Neish, Ph.D.

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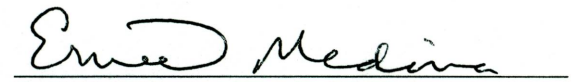

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ABSTRACT

Obesity is a significant United States' public health concern. This study examined whether a clinic-based obesity treatment program, focused on body composition change through resistance training, lead to improved body composition, exercise behaviors, and attitude change from focus on weight loss to body composition change. Improvements in self-efficacy, outcome expectations and stages of change were also examined. Forty-eight physician-referred overweight or obese adult women (mean body fat 41%, SD = 6.65%), completed assessments and questionnaires at baseline and three months. Significant improvements across groups existed for attitude (22.31, SD = 3.45 to 24.25, SD = 2.72; $p \leq 0.001$), stages of change (2.44, SD = 1.01 to 2.77, SD = 0.99; $p<0.05$), outcome expectations (28.69, SD = 3.48 to 30.42, SD = 3.54; $p<0.05$), days exercised (2.01, SD = 2.0 to 2.71, SD = 2.13; $p<0.05$), and exercise type (resistance 4.2 to 8.3%; aerobic and resistance 20.8 to 50%, $p<0.05$). Although there were no significant improvements in body composition, this study demonstrates that, for certain people, a body composition focused obesity management program can be successful at promoting stages of change progression, improved attitude and self-efficacy, increased resistance training exercise and days spent exercising.

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INTRODUCTION

Obesity is a significant public health concern with over 61% of those living in the United States overweight or obese (Wyatt, 2003). Obesity is associated with an increase in morbidity including type 2 diabetes (Albu and Raja-Khan, 2003; Bloomgarden, 2003; Despres, 1998; Zimmet, 2003), coronary heart disease (Anderson, Kendall et al., 2003; Barton and Furrer, 2003; Manson, Willett et al., 1995), and various cancers (Ballard-Barbash and Swanson, 1996; Bray, 2003; Giovannucci, Colditz et al., 1996).

While most obesity treatment has focused on lowering caloric intake, along with improving exercise activity and behavioral changes such as counting calories, individuals continue to focus on absolute weight loss as a key outcome. Weight and low calorie focused treatments often result in loss of fat free mass leading to a decrease in resting metabolic rate causing weight loss and maintenance to be even more difficult (Banz, Maher et al., 2003; Marks and Rippe, 1996). However, when resistance training is incorporated, even without the loss of absolute weight, fat free mass is maintained or increased (Banz et al., 2003; Park, Park et al., 2003; Ross, Freeman et al., 2000; Tsutsumi, Don et al., 1997). Client understanding of resistance training mechanisms to increase muscle and decrease fat mass, and how these changes in body composition affect health and metabolism, may lead to an improvement in their obesity management. This is a varied approach from the traditional absolute weight loss intervention which often leads to a decrease in metabolism resulting from a loss of muscle mass making weight maintenance and continued overall fat loss more difficult (Ross et al., 2000; Tsutsumi et al., 1997).

Weight management programs are often accompanied by high attrition rates. In a meta-analysis study of 20 behavioral change programs, including weight loss, one in three participants dropped out before completing the behavioral treatments (Davis and Addis, 1999). This finding was supported by yet another study that looked specifically at attrition and retention rates of a large clinic based weight-focused program (Honas, Early et al., 2003). The results indicated, at the 16-week intervention period, 31% of participants had dropped out while 69% remained. Key indicators for attrition, based on relative risk (95% confidence intervals), included patients who were female, 1.32 (1.01-1.73), less than 40 years of age, 1.66 (1.27-2.18) and between the ages of 40 to 50 years, 1.33 (1.01-1.76). Riebe and colleagues (2003) showed similar results when assessing a behavioral and lifestyle-focused weight change program, with only 76% of participants completing the six-month intervention.

Along with these attrition rates, only a moderate amount of weight was lost in weight-focused programs. Typically, between five to 10 percent of initial weight is lost, with most of the change occurring in the first three months of intervention (Davis and Addis, 1999; Riebe, Greene et al., 2003; Rosenblatt, 1988). As indicated, moderate weight change, high attrition rates, lowered metabolic rate and loss of muscle mass, found in traditional weight-focused programs, accompanied by a continuous rise in the United States overweight and obesity rates, necessitates a need for an improved obesity intervention.

Theoretical Framework

Because physical activity, notably resistance exercise, reduces the loss of and maintains fat free mass, it is important that physical activity be included in obesity

treatment. However, it has been reported that 60% of the United States population did not meet the minimal physical activity requirements or were not active at all (Satcher, Lee et al., 1999; Thompson, 2002). When compared to aerobic exercise, resistance exercise has shown to have the greatest effect on reducing overall body fat and maintaining or improving muscle mass, while aerobic exercise resulted in a greater loss of absolute weight (Banz et al., 2003; Park et al., 2003).

Improving self-efficacy and progressing through the stages of change to action and maintenance can further influence adoption of physical activity (McAuley and Blissmer, 2000), potentially leading to a healthy body composition. As part of the *social cognitive theory*, self-efficacy is a significant contributing factor to the choice, effort, and persistence individuals elicit for any activity (Bandura, 1997; McAuley and Blissmer, 2000). Especially in the early stages of exercise adoption and into maintenance, self-efficacy affects health behaviors directed at choosing a physical activity, such as overcoming obstacles like weather and vacation (Marcus and Owen, 1992; McAuley and Blissmer, 2000). Self-efficacy can also be a powerful indicator of who will complete behavioral change programs (Davis and Addis, 1999). Outcome expectations, another variable in the *social cognitive theory*, are the beliefs that specific outcomes will be affected by personal action, such as decreasing body fat by participating in regular resistance training exercise (Bandura, 1997). Together, self-efficacy and outcome expectations play a powerful role in determining which course of action individuals choose in adopting a health behavior and resulting consequences.

The stages of change component of the *transtheoretical model* has been studied extensively in relation to exercise behavior across various populations (Bock, Marcus et

al., 1998; Cardinal, 1995; Marcus, Banspach et al., 1992a; Marcus, Pinto et al., 1994; Marcus and Simkin, 1994; Prochaska, Velicer et al., 1994b; Riebe et al., 2003; Rodgers, Courneya et al., 2001). The five stages, as related to resistance training, are identified as: Precontemplation (not thinking about making change), Contemplation (thinking about making a change within six months), Preparation (actual making a small change), Action (engaging in resistance training for 0-6 months), and Maintenance (continuation of resistance training beyond 6 months) (Marcus et al., 1994; Prochaska et al., 1994b). The focus is on the actual behavior, resistance training, and intention to perform that behavior (Marcus et al., 1994). Self-efficacy also influences the progression through the stages of change. Individuals in precontemplation and maintenance showed the lowest and highest self-efficacy scores, respectively (Cardinal, 1997; Marcus and Owen, 1992; Marcus, Selby et al., 1992b).

While self-efficacy and outcome expectations play a powerful role in determining which course of action individuals choose in adopting a health behavior, self-efficacy often varies with each stage of change. For this study, self-efficacy, outcome expectations and stages of change were assessed in relation to a body composition focused intervention to obesity management. These items were measured to determine whether self-efficacy for resistance training influenced subject's outcome expectations of a decreased in body fat and stage of change in relation to beginning a body composition focused intervention.

Support

Both group and individual support during a behavior change provide different aspects of intervention that include a varied social and targeted approach. Group

interventions generally provide social interaction and support while individual sessions offer a more personalized targeted approach to behavior change and support (Di Loreto, Fanelli et al., 2003; Hayaki and Brownell, 1996; Moe, Elliot et al., 2002). Group sessions, when used during a weight loss program, lead to a faster loss of weight. However, individual sessions resulted in a greater maintained weight loss (Hakala, Karvetti et al., 1993). This is likely the result of maintained personalized intervention. The difference between group and combined group and individual support has not been addressed when the focus is on body composition change as the primary outcome instead of weight loss.

It is important, when developing an obesity treatment program, to provide the obese individual with a mechanism to maintain or increase fat-free mass positively influencing metabolism, while improving self-efficacy related to a specific physical activity, namely resistance training. A program that can show a movement through the stages of change toward the action stage may be more successful at achieving adoption of physical fitness and improving body composition while reducing obesity, helping to maintain or increase metabolism by increasing fat-free mass.

METHOD

Setting

Telephone recruitment of subjects took place July 1, 2001 through February 28, 2002 from clients who enrolled in the *Total Wellness* obesity treatment program at Beaver Medical Group, Redlands, California and medical clinics affiliated with Beaver Medical Group. Beaver Medical Group is a clinic-based establishment with over 25 specialties and subspecialties.

Study Design

The investigation employed an experimental pretest-posttest design with random assignment to: 1) *Total Wellness* support group only (SG) (n=24), or 2) *Total Wellness* support group plus individual appointments (SG + I) (n=24) in a body composition focused obesity management program. SG subjects were instructed to attend the initial *Total Wellness* class along with one support group. The SG + I subjects were instructed to attend the initial *Total Wellness* class, one support group and one individual support session. Assessments of change in attitude, self-efficacy, outcome expectations, stage of change, body composition, and exercise behavior took place within one week prior to *Total Wellness* intervention, between the months of August and February, and within one week following the three-month intervention. A post-hoc follow-up at one-year assessed stages of change, self-efficacy, attitude and exercise behavior. These data were collected via telephone interview.

Subjects

Prior to data collection, the Loma Linda University Institutional Review Board (IRB) and Beaver Medical Group IRB approved this study. Subject's consents were obtained and explanation of California human subject bill of rights given prior to administering the study instruments. Subjects were included if they were 21 years of age or older; met overweight or obesity status, based on physician diagnosis and/or body composition measurement of at least 28% body fat (Nieman, 1995); had no current participation in any other weight loss treatment (medical, dietary or behavioral) within the past one month; and completed PAR-Q form (Balady, Berra et al., 2000) with no

answers indicating activity restriction based on health status unless referred by physician and signed the informed consent document.

One hundred fourteen male and female subjects consented and met criteria to participate in this study. However, after a 58% dropout or non-compliance to study protocol, and exclusion of the remaining two males for generalization to a female population, the study population consisted of 48 women (42% of original subjects). The study population subjects' body fat ranged between 28-50% with an average age of 47.63 years (SD = 12.14). Subjects were evenly divided with 24 women in the SG group and 24 women in the SG+I group with no differences in drop-out rates between SG and SG + I groups. Subject characteristics are summarized in Table 1.

Intervention

All subjects attended the *Total Wellness* obesity intervention class following completion of the pre-intervention assessments. Each subject was then randomly assigned to one of two intervention groups: support group (SG) or support group plus individual support (SG + I). SG subjects were instructed to attend at least one *Total Wellness* support group over the course of the three-month intervention period. SG + I subjects were instructed to attend at least one support group plus one individual support session.

The curriculum for the *Total Wellness* class consisted of an emphasis on balanced nutritional intake, focus on body composition change in place of absolute weight loss, and the importance of resistance training including improved muscle mass, decreased fat mass, and increased strength. Also discussed were demonstrations using dumb bells, resistance bands and other resistance equipment, proper technique and recommended

length of exercise sessions for optimal results related specifically to resistance training. Each support group class again emphasized the importance of resistance training, demonstrated examples and proper technique of basic resistance exercises for upper and lower body, and the importance of emphasis on body composition change, namely increased muscle and decreased fat mass, in place of absolute weight reduction. The support groups also focused on planning resistance exercise sessions into subjects' schedules with recommendations to the entire group, not individuals. The *Total Wellness* support group size ranged from five to 20 subjects and additional routine clinic patients. Individual support group sessions focused on specific needs of the subject pertaining to balanced nutrition, demonstrated examples and proper technique of basic resistance exercises for upper and lower body, and planning resistance exercise sessions into subject's individual schedules. Individual support sessions were one-on-one with the subject and primary investigator or preventive care specialist at the clinic. Post-intervention assessments were completed three months following the pre-intervention assessment. Subjects who completed pre- and post-intervention assessments along with outlined three-month intervention were given exercise resistance bands and water bottles as appreciation for participation.

A one-year post-hoc assessed stages of change, self-efficacy, attitude and exercise behavior. Subjects were surveyed via telephone once verbal consent had been obtained. Twenty-one participants from the original 48 subjects (44%) completed the one-year follow-up assessments.

Measurements

Pre, post and one-year follow-up questionnaires were developed to assess five outcome variables: 1) stages of change from the transtheoretical model (Prochaska and Velicer, 1997a); 2) self-efficacy for resistance training; 3) outcome expectations related to resistance training as part of the social cognitive theory (Bandura, 1977; Bandura, 2001; Bandura, Adams et al., 1977); 4) attitude toward resistance training; and 5) resistance and aerobic exercise behavior. Body composition was also measured. These assessments took place within one-week pre-intervention and within one-week following the three-month intervention period. The one-year follow-up study assessed self-reported stages of change, self-efficacy, attitude and exercise behavior.

Anthropometrics. Body composition was measured using the Tanita bioelectrical impedance monitor, model TBF300, as well as the seven-site skin fold caliper measurement of the triceps, biceps, subscapula, suprailiac, chest, abdomen and thigh. Weight was included, measured to the nearest 0.5 pound, on the Tanita bioelectrical impedance monitor. Body density was calculated using the Jackson-Pollack equation (Balady et al., 2000; Jackson and Pollack, 1985). Body fat was then estimated using the Siri formula (Balady et al., 2000).

Stages of Change. We developed the stage of change scale following Prochaska's guidelines, with special emphasis on specific behaviors related to resistance training, not physical activity in general (Prochaska, Norcross et al., 1994a; Prochaska and Velicer, 1997a; Prochaska and Velicer, 1997b). We constructed the stage of change scale using two existing scales: the *Stage of Exercise Adoption Scale* (Marcus et al., 1994; Marcus and Simkin, 1994) with a Kappa index reliability of 0.78; and the *Exercise*

Stages of Change Short Form Scale (Marcus et al., 1992b) with a Kappa index reliability of 0.78.

We developed the stage of change scale based on the existing scales mentioned above, using five questions related to current participation in resistance training activity. Questions assessed precontemplation, contemplation, preparation, action or maintenance phase.

Self-Efficacy. Self-efficacy instruments, specific to exercise and physical activity, exist and have been validated across various populations (Bernier, 1986; Clark, Abrams et al., 1991; Marcus et al., 1992b; McAuley, 1992; McAuley and Blissmer, 2000; McAuley, Lox et al., 1993; Sallis, Haskell et al., 1986). The assessment of self-efficacy was developed using three existing exercise self-efficacy scales: the five-item *Exercise Self-Efficacy Scale* (Marcus, Selby et al., 1992c) with a Cronbach's alpha range of 0.773 to 0.869; and a three-population five-item exercise self-efficacy scale (Rodgers et al., 2001) with Cronbach's alpha of 0.76; and *McAuley's 13-Item Exercise Self-Efficacy Questionnaire* (McAuley, 1992) with a Cronbach's alpha of 0.88.

The instrument, developed from the above three scales, measured self-efficacy for resistance training using a five-point Likert-type scale with 1 indicating low self-efficacy and 5 indicating high self-efficacy. The nine items were designed to address typical factors affecting participation in resistance training activity including weather, mood, schedule change and convenience. Internal reliability of the nine-item resistance training self-efficacy questionnaire was excellent based on Cronbach's alphas of .86 and .91 for baseline and 3-month post-treatment questionnaires, respectively.

Outcome Expectations. The outcome expectations instrument followed guidelines outlined by Bandura on how to assess outcome expectations within the *social cognitive theory* (Bandura, 1997, 2001). Outcome expectations, specific to results anticipated by participating in the *Total Wellness* program for resistance training, were measured using a five-point Likert-type scale with 1 indicating "strongly disagree" and 5 indicating "strongly agree". The eight items addressed weight and body composition change, exercise type, and dietary intake. Positively and negatively worded questions were arranged randomly to reduce response bias after reverse scoring of items three, four and eight and deleting item three. Initial internal reliability of the eight-item resistance training focused *Total Wellness* program outcome expectations instrument was reasonable based on Cronbach's alphas for the baseline and 3-month post-treatment questionnaires, 0.61 and 0.65 respectively.

Attitude. Attitude, specific to weight, body composition and dietary intake change as discussed in the *Total Wellness* program, was assessed using a six-item, five-point Likert-type scale with 1 indicating "strongly disagree" and 5 indicating "strongly agree". Positively and negatively worded questions were arranged randomly to reduce response bias. After reverse scoring of items two and five and deleting item five because of low internal reliability, internal reliability of the six-item resistance training focused attitude instrument, based on Cronbach's alphas for the baseline and 3-month post-treatment questionnaires, remained low at 0.50 and 0.49, respectively.

Exercise Behavior. Exercise behavior was assessed using three questions addressing 1) number of days per week exercise performed, 2) average minutes per day spent in exercise, and 3) type of exercise performed, whether resistance, aerobic or both.

The one-year follow-up questionnaire also assessed which, if any, type of exercise had increased: resistance, aerobic, both or none.

Data Analysis. Data entry and statistical analysis were performed using Statistical Package for the Social Sciences (SPSS Version 10.0). Reported p values are two-tailed with $\alpha = 0.05$.

Descriptive statistics were used to summarize subject demographic data. Independent t-tests for two groups were used to assess differences between SG and SG+I groups on all continuous level variables at post-treatment. No significant differences were found on any variables between groups, therefore SG and SG + I groups were collapsed. ANOVA controlling for baseline values, was performed on the three-month post-intervention data. In addition, paired t-tests were used to assess pre- and post-test differences among dependent variables. Again, because no significant differences were found on any variables between SG and SG + I groups, the results were collapsed across groups. Comparison of mean self-efficacy by stage of change and type of exercise was also performed using t-tests.

Cross tabulations and chi-square were used for stage of change and type of exercise. Pearson correlations were used to determine linear associations among self-efficacy, stage of change, outcome expectation, attitude change and exercise behaviors for pre- and post-intervention data.

RESULTS

Demographic Data

The study population (n=48) consisted of women ages 33-68 years. All subjects were considered overweight or obese with a body fat of 28% or greater (Nieman, 1995)

with individual body fat range between 28-50%. Subject characteristics are included in Table I.

Measurements

Anthropometrics. A subset of nine subjects (19%), of the 48, lost a clinically significant amount of body fat of more than or equal to 1.9% from pre- to post-intervention. The nine subjects' mean pre to post change in body fat was -3.74% (SD = 2.83%), $\underline{p} = 0.004$. Pre to post mean weight loss for this same subset was not significant.

Overall, no significant differences were found comparing mean change in body fat, fat free mass or weight between baseline and 3-months post-assessment or between SG and SG + I groups. Results are presented in Table I. ANOVA results showed a significant interaction between pre-type of exercise (none, aerobic, resistance, both) and pre- and post-body fat percentage ($F (3, 47) = 4.1$, $\underline{p} = 0.012$ and $F (3, 47) = 3.6$, $\underline{p} = 0.021$, respectively). Those subjects at baseline who participated in both resistance and aerobic type exercise showed the greatest decrease in body fat from baseline to 3-months post-intervention. ANOVA results also show a significant interaction between baseline stage of change and baseline body fat percentage ($F (4, 47) = 2.987$, $\underline{p} = 0.029$), with body fat percentage being lowest in the maintenance stage and highest in the precontemplation stage. In addition, subjects in contemplation or preparation stage at baseline had a decrease in body fat percentage by 3-months post-assessment, while subjects in the other stages at baseline, especially precontemplation, had an increase in body fat percentage by 3-months post-assessment.

Exercise Behavior. The number of days per week exercise was performed increased significantly from baseline (2.01) to 3-months (2.71) ($p = <0.05$). Minutes per day did not show a significant change.

Stages of Change. There was a significant change between baseline and 3-months post-assessment stage of change ($\chi^2 = 31.831$), $p = 0.011$. Forty-two percent of subjects (n = 21) progressed from their baseline stage of change. Based on chi-square results ($p = 0.011$), of these 21 subjects, three (14%) moved from precontemplation into contemplation or preparation, while six (29%) moved from contemplation into preparation and three into action phase. In addition, five subjects (24%) progressed from preparation into action, while one subject moved from action into maintenance phase. Overall, seven subjects (14.6%) regressed from baseline to 3-months of this study while 20 (41.7%) showed no stage change. Refer to Table I.

Self-Efficacy. The mean self-efficacy scores, for those subjects in action (n = 8) or maintenance (n = 2) phase at 3-months post-intervention, increased significantly (from 25.50 to 29.62 and 31.50 to 33.50, respectively), based on ANOVA results, $p = 0.015$, while those subjects in the precontemplation, contemplation or preparation stage decreased at 3-months post-assessment ($p = 0.015$). Subjects' self-efficacy decreased from baseline to 3-months post-intervention in all types of exercise groups, $p = 0.014$. Refer to Table II and III.

Outcome Expectations. Overall, the paired t-test indicated a significant increase from the baseline (28.69, SD = 3.48) to 3-months post-intervention (30.42, SD = 3.54) means for outcome expectations, $p = 0.031$. Refer to Table I.

Attitude. Paired t-tests indicated a significant improvement between baseline and 3-months post-intervention scores across groups (22.31, SD = 3.45; 24.25, SD = 2.72, respectively), $p = 0.001$. Paired t-tests showed significant improvements in attitude toward a body composition focused obesity program on three individual instrument items from baseline to 3-months post-intervention. Results for individual items are presented in Table IV.

One-Year Follow-Up Measurements

Instruments for the one-year follow-up assessed stage of change, self-efficacy and attitude. The decision to add a follow-up was post-hoc. At the time of the telephone interview, subjects were also given the opportunity to make an appointment for measurement of body composition. Because no subjects requested this measurement, outcome data for anthropometrics were not collected. Twenty-one subjects responded (19%) with 11 from SG group and 10 from SG + I group.

Stage of Change. Although not statistically significant, all subjects in the precontemplation, contemplation or preparation stage at the three-month assessment had progressed to the next stage, contemplation, preparation or action phase, respectively, at the one-year assessment.

Self-Efficacy. Paired t-test results showed a non-significant increase in self-efficacy from baseline to one-year and 3-month to 1-year means, although self-efficacy scores continued to increase from the 3-month assessment (25.76) to the 1-year follow-up (26.86).

Attitude. Paired t-test indicated a significant decrease between the baseline and 1-year mean scores (from 21.90, SD = 2.95 to 15.76, SD = 1.89, $p \leq 0.0001$) as well as

the 3-month and 1-year mean scores (from 23.14, SD = 3.21 to 15.76, SD = 1.89, $p \leq 0.0001$).

DISCUSSION

Strengths

The current study showed significant improvements, by 3 months, during a body composition focused obesity management program in the areas of attitude (from 22.31, SD = 3.45 to 24.25, SD = 2.72; $p \leq 0.001$), stages of change (2.44, SD = 1.01 to 2.77, SD = 0.99; $p<0.05$), outcome expectations (from 28.69, SD = 3.48 to 30.42, SD = 3.54; $p<0.05$), days of the week exercised (from 2.01, SD = 2.0 to 2.71, SD = 2.13; $p<0.05$), and percent engaging in exercise (resistance only from 4.2 to 8.3%; aerobic and resistance from 20.8 to 50%, $p<0.05$). However, there were no significant improvements in body composition.

This study is the first we are aware of that compared two intervention groups focused on body composition change, instead of on absolute weight loss, during an obesity management program. Although no differences were found between the SG and SG + I groups and the sample size was small, a strength of this study was the comparison of two randomly assigned intervention groups. Similar to a recent study (Riebe et al., 2003), this study also emphasized a lifestyle change through a decreased intake of calories and focus on body fat loss and muscle gain. However, the current study focused on increased resistance training exercise to improve body composition, and de-emphasized a change in weight. In addition, subjects in the SG+I group received counseling specific to their individual needs, emphasizing the above items.

This current study also applied components from both the *transtheoretical model* (Prochaska and Velicer, 1997a) and *social cognitive theory* (Bandura, 1977; Bandura, 2001). In a similar study using the *transtheoretical model*, authors assessed stages of change prior to intervention; however, progression through the stages was not reassessed at post-intervention (Riebe et al., 2003). Therefore, it is not known if subjects made progress while in the intervention phase. Similar to the study by Riebe et al, the highest percentage of subjects at baseline, for the current study, were in the contemplation stage (39.6%). Across groups, the majority of subjects' (58.4%) progressed to a higher stage from baseline to the three-month assessment. Attitude and outcome expectations related to an obesity management program focused on body composition change also improved at the 3-month assessment. Self-efficacy, although not significantly different from baseline, continued to increase from the 3-month assessment to the one-year follow-up.

Also, although the overall change in body fat percentage was not significant, there was a subset of nine subjects (19%) who did lose a significant percentage of body fat by three-months. Change in weight was not significant. This change, or lack thereof, in a key dependent variable of obesity treatment is consistent with findings by Riebe et al (2003). One main difference, however, is the focus on body composition change for this current study, whereas most other studies focus on weight change for obesity management.

The confounding effect of history was controlled for by testing several groups of subjects over a nine month time period, August through April. This period included several major holidays that often lead to lifestyle and body composition awareness, specifically Thanksgiving, Christmas and New Years. Subjects taking part in

intervention during these months (n=24) showed no significant difference on change in body fat percentage, post-stage of change, self-efficacy, outcome expectations, and attitude between those subjects in other non-major holiday months (n=24).

Another strength was the one-year follow-up assessment, although the response rate was low (44%) possibly due to post-hoc addition of this assessment. Similar to a study looking at maintenance of exercise and weight change following a period of six-month intervention (Borg, Kukkonen-Harjula et al., 2002), the one-year follow-up indicated poor adherence to exercise, whether resistance or aerobic.

Limitations

One limitation of the current study was the low internal reliability of the attitude questionnaire, designed to assess a change in attitude related to obesity management from a focus on absolute weight loss to a focus on body composition change. The attitude questions were newly developed specific for this study and the *Total Wellness* class and had not been assessed prior to this study. The six-item questionnaire assessed attitude toward increased weight through muscle gain, loss of body fat and diet. Using a questionnaire with a greater number and selection of questions may have shown a greater internal consistency and perhaps a change in attitudes of the subjects. In addition, although subjects were encouraged to continue in the *Total Wellness* program following the 3-month intervention, the significant drop in attitude scores may have been due to subjects' lack of support for resistance training once the study was completed. Also, because the intervention was limited to three months and the concept of focusing on body composition change through resistance training in place of absolute weight loss was new, a positive change in attitude toward a body composition change through resistance

training may take longer than three months and demand more intervention than was required in this study.

Self-efficacy decreased for subjects in all types of exercise at three-months post-intervention as well as for subjects in the precontemplation, contemplation or preparation stage at 3-months post-intervention. However, self-efficacy did increase for those subjects in the action or maintenance stage at 3-months. Following health behavioral change programs, an improvement in self-efficacy is usually noted (Clark and Dodge, 1999). Perhaps, because concepts related to changing body composition in place of weight loss were new to subjects and subjects were required to attend only one *Total Wellness* class and Support Group, those who remained in the lower stages of change at 3-months post-intervention did not receive enough exposure to the new concepts to improve self-efficacy. It is recommended that increasing subject's attendance to the *Total Wellness* classes, for future study, may result in increased self-efficacy scores between baseline and post-intervention assessment.

Because the subject population was women only, typically the highest proportion of weight management programs, generalization of findings is limited to women. Due to dropout from intervention, only a very small sample size of men (n=2) remained at three-months post-intervention. Importantly, this is supported by several studies that noted 1 in 3 participants dropped out before completion of the behavioral program (Davis and Addis, 1999) and found key indicators for attrition include patients who were female and between the ages of 40 to 50 (Honas et al., 2003). To make results generalizable to a female population, results were based on the remaining 48 women only. Dropout rates were high from baseline to 3-months and 3-months to 1-year assessments. Modification

of future studies regarding the *Total Wellness* program by requiring subjects to attend a greater number of support and individual groups, may improve dropout rates with subjects receiving more support as they focus on obesity management.

Lastly, the three-month intervention period, and one *Total Wellness* class and support group session, may have been too short and not intense enough to decrease body fat significantly. In a similar study, it was noted that most of the decrease in weight and body fat occurred during the first three months (Riebe et al., 2003). However, length of intervention seen in several other obesity change studies is at least six months (Bacon, Keim et al., 2002; Borg et al., 2002; Riebe et al., 2003).

RECOMMENDATIONS

For Research

1. Measure the effectiveness of this type of obesity intervention that focuses on body composition in other populations, such as men or adolescents.
2. Compare the effectiveness of this body composition focused intervention to a weight loss focused intervention.
3. Conduct a one-year follow-up that is not based solely on self-reported outcomes and includes a larger number of subjects from the intervention.

For Practice

1. While the overall effect of this intervention did not show significant changes for self-efficacy or body fat percentage, attitude, outcome expectations, the proportion of subjects moving up at least one stage of change, and frequency of exercise did improve significantly from baseline to three-month post assessment across groups. Other variables may take a longer period of time to show improved change, if at all. However,

with an improvement in attitude and outcome expectations toward a focus in body composition change, a positive progression through the stages of change, and increased frequency of exercise, actions taken toward resistance training are more likely to occur following this body composition focused intervention, but need reinforcement over time to maintain.

2. The subset of nine women (19%) who did lose a significant percentage of body fat can be viewed as a positive change. Incorporation of this body composition focused intervention into a weight loss focused setting may improve overall effectiveness by capturing a larger population subset of individuals who improve their obesity status, based on body composition and/or weight.

3. Intervention took place over a three-month period. This duration may not be long enough to show significant differences in the specific variables studied. Also, subjects were instructed to attend only one support group, which may not be sufficient to significantly affect outcome variables. Therefore, it is suggested that a body composition focused obesity management program take place over a longer period of intervention and involve participants in more support group or individual sessions.

CONCLUSION

A clinic based body composition focused intervention program, that also incorporates change in exercise and dietary behavior, was successful at promoting significant body composition change in 19% of the female subjects. While overall changes were not significant between the support group and support plus individual group, when groups were combined, attitude, stage of change, outcome expectations, and frequency of exercise increased significantly from baseline to 3-months post intervention.

The current study demonstrates that a body composition focused obesity management program can be successful at promoting a change in body composition. However, in agreement with other obesity management studies, the significant change may be evident in only a small proportion of the overweight or obese population.

TABLES

Table I. *Comparison of Baseline and Follow-Up Measurements Collapsed Across Support Group and Support Group Plus Individual Appointment Groups.*

	Baseline n=48	**3-Month follow-up** n=48
Dependent variable	Mean or % (SD)	Mean or % (SD)
Stage of change*		
Precontemplation	16.7%	10.4%
Contemplation	39.6	27.1
Preparation	31.3	41.7
Action	8.3	16.7
Maintenance	4.2	4.2
Self-efficacy	25.96 (7.02)	24.81 (8.18)
Range	9-38	9-45
Outcome expectations*	28.69 (3.48)	30.42 (3.54)
Range	24-36	22-40
Attitude**	22.31 (3.45)	24.25 (2.72)
Range	14-30	17-30
Body fat (%)	41.70 (6.65)	41.27 (7.32)
Weight (lbs)	200.36 (60.53)	200.00 (59.76)
Exercise behavior		
Days/wk*	2.01 (2.00)	2.71 (2.13)
Minutes/day	2.33 (1.43)	2.29 (1.22)
Type of exercise*		
None	37.5%	14.6%
Aerobic	37.5	27.1
Resistance	4.2	8.3
Aerobic & resistance	20.8	50.0

*$p < 0.05$. **$p \leq 0.001$

Table II. *Mean Differences in Self-Efficacy Across Type of Exercise at Baseline and Three Months.*

Type of exercise	Self-efficacy mean	n
None		
Baseline	23.83	18
3-Month	22.00*	12
Aerobic		
Baseline	26.33	18
3-Month	20.15*	9
Resistance		
Baseline	24.00	2
3-Month	23.00*	6
Both (aerobic/resistance)		
Baseline	29.50	10
3-Month	28.46*	21

* $p < 0.05$.

Table III. *Mean Differences in Self-Efficacy Across Stages of Change at Three Months.*

Stage of change	Self-efficacy	n
Precontemplation		
Baseline	21.20	5
3-Month	16.20*	5
Contemplation		
Baseline	23.23	13
3-Month	22.85*	13
Preparation		
Baseline	28.55	20
3-Month	25.45*	20
Action		
Baseline	25.50	8
3-Month	29.62*	8
Maintenance		
Baseline	31.30	2
3-Month	33.50*	2

* $p < 0.05$.

Table IV. *Attitude Questionnaire: Item Means With Baseline and Three-Month Differences.*

Attitude item	Mean (SD)	3-Month – baseline difference (SD)
Treating my overweight/obesity means:		
1. Adding muscle causing potential body weight gain.		+0.54 (1.32)
Baseline	3.31 (1.19)	
3-Month	3.85 (1.15)	
2. Not adding muscle so body weight does not increase.		+0.21 (1.35)
Baseline	3.46 (1.13)	
3-Month	3.67 (1.24)	
3. Adding muscle through resistance training.		+0.40 (0.89)**
Baseline	3.94 (0.91)	
3-Month	4.33 (0.66)	
4. Losing body fat.		-0.02 (0.84)
Baseline	4.60 (0.57)	
3-Month	4.58 (0.71)	
5. Consuming a very low calorie diet.		+0.50 (2.20)
Baseline	2.73 (1.22)	
3-Month	3.23 (1.31)	
6. Consuming a variety of healthy food, carbohydrates, proteins, fats.		+0.31 (0.88)*
Baseline	4.27 (0.84)	
3-Month	4.58 (0.50)	

*$\underline{p}$ = <0.05. **$\underline{p}$ <0.01
Total n = 48. Possible score range = 1 disagree-5 agree.

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CHAPTER 5

OTHER FINDINGS

A. Introduction

Due to the specific regulations of the chosen journal, the previous chapter did not include all information important to this study. Therefore, this chapter will include and discuss additional findings pertinent to this study.

B. Item Analysis

1. Exercise Behaviors

Exercise behavior was assessed using three questions addressing 1) number of days per week exercise performed, 2) average minutes per day spent in exercise, and 3) type of exercise, whether resistance, aerobic, both or none. Days per week increased significantly from baseline (2.01, SD = 2.00) to 3-months (2.71, SD = 2.13), $p = <0.05$. As would be expected, following the *Total Wellness Program*, the number of subjects in the resistance and aerobic/resistance type of exercise groups both increased significantly from baseline (n = 2 and 10 respectively) to 3-months (n = 4, 24, respectively) based on chi square results, $p < 0.001$. In addition, the number of subjects in the none and aerobic only exercise groups decreased over time from baseline (n = 18, 18, respectively) to 3-months (n = 7, 13, respectively), $p <0.001$. Although not significant, body fat percentage decreased for the aerobic (43.47 to 42.39) and aerobic/resistance (39.65 to 39.10) groups while body fat percentage increased for the none (43.27 to 44.09) and resistance only (45.53 to 45.68) groups, based on post-type of exercise. Results indicated that, for the 21 subjects who took part in the one-year follow-up study, 42.9% (from 19% at 3-months) were doing aerobic only exercise, none (from 9.5%) continued resistance only, 42.9%

(from 52.4%) were doing aerobic and resistance and 14.3% (from 19%) were doing no exercise. However, minutes per day and days per week increased slightly from 3-month values, although not significantly.(Refer to Table 1.)

2. Stages of Change

Questions in the stage of change instrument were worded specific to resistance training exercise and reflected each of the five stages from precontemplation to maintenance. Overall, 21 subjects (44%) advanced through the stages. Twenty subjects (42%) remained at the same stage at the 3-month assessment. Therefore, 41 subjects either moved forward or not at all, while just seven regressed through the stages of change.

Nineteen (39.6%) of the subjects began the study in the contemplation stage with six progressing from contemplation to preparation and three to action phase, while 15 subjects (31.3%) started in preparation, five moving to action phase. Based on ANOVA, a decrease in body fat percentage was seen in the subjects who began in contemplation or preparation stage and moved forward at least one stage. All other subjects showed an increase in body fat percentage from baseline to 3-months (baseline-body fat across baseline-stage of change $F = 2.987$, $p = 0.029$). Based on chi square results, those subjects who were in contemplation or preparation stage at 3-months (54%) were also more likely to be in the none or aerobic baseline-type of exercise ($p = 0.0003$), while those who were in the preparation stage at 3-months were more likely to have moved to the aerobic and resistance type of exercise at baseline ($p = 0.003$). Movement through the stages was statistically significant across groups. Self-efficacy scores, across stages of change, also showed significance when based on post-efficacy and post-stage ANOVA

results ($F = 3.461$, $p = 0.015$). Subjects who were in the action or maintenance stage at post-intervention showed improvements in self-efficacy scores from pre to post-assessment. Although not significant, the only subjects showing a positive change in self-efficacy scores, across pre-stage of change, were those who were in maintenance stage at baseline. (Refer to table 2.)

One-year data indicated that ($n = 21$), although not statistically significant because of low power, subjects in precontemplation ($n = 1$), contemplation ($n = 4$) or preparation ($n = 2$) stage at the 3-month assessment, progressed to a higher stage of change at the one-year assessment. (Refer to Table 1.)

Table 1. *Comparison of One-Year Follow-Up Measurements to Three-Month Measurements.*

	3-Month n=21	1-Year follow-up n=21
Dependent Variable	Mean or % (SD)	Mean or % (SD)
Stage of change		
Precontemplation	4.8%	4.8%
Contemplation	38.1	42.9
Preparation	28.6	14.3
Action	19.0	28.6
Maintenance	9.5	9.5
Self-efficacy	25.76 (8.10)	26.86 (7.77)
Attitude	23.14 (3.21)	15.76 (1.89)
Exercise behavior		
Days/wk	2.57 (2.25)	3.05 (1.77)
Minutes/day	2.57 (1.43)	2.62 (1.40)
Type of exercise		
None	19.0%	14.3%
Aerobic	19.0	42.9
Resistance	9.5	0.0
Aerobic & resistance	52.4	42.9

Table 2. *Association of Stages of Change and Type of Exercise at Baseline and Three Months.*

Stage of change	Type of exercise			
	None	*Aerobic*	*Resistance*	*Both aerobic/resistance*
Precontemplation*				
Baseline	5	3	0	0
3-Month	1	4	0	0
Contemplation*				
Baseline	11	8	0	0
3-Month	4	7	1	1
Preparation*				
Baseline	2	5	1	7
3-Month	2	1	2	15
Action*				
Baseline	0	1	0	3
3-Month	0	1	1	6
Maintenance*				
Baseline	0	1	1	0
3-Month	0	0	2	2

*Chi square pre-type of exercise across pre-stage of change: $p < 0.001$.
**Chi square post-type of exercise across post-stage of change: $p < 0.01$.

3. Self-Efficacy

The nine questions in the self-efficacy scale addressed situations that might affect resistance training exercise. Situations included weather changes, mood, illness and support. Of a total possible score of 45, subject's scores ranged from 9 to 38 at baseline and 9 to 45 for the 3-month assessment. Overall, self-efficacy change was not significant. ANOVA results showed self-efficacy scores decreased for all baseline (NS) and 3-month assessment exercise groups, with baseline-self-efficacy scores across 3-month assessment type of exercise ($F = 4.838$, $p = 0.005$) and 3-month-self-efficacy scores across 3-month type exercise ($F = 3.971$, $p = 0.014$) being significant. As noted above under *Stages of Change*, improvements in self-efficacy were also seen in subjects who were in the 3-month assessment action or maintenance stage.

4. Outcome Expectations

The eight items in the outcome expectations questionnaire were designed to address key topics discussed in the *Total Wellness* classes. Scores ranged from 24 to 36 for baseline and 22 to 40 for 3-month assessment. The total possible score was 40. Overall, there was a significant increase in means from the baseline (28.69, SD = 3.48) to 3-month (30.42, SD = 3.54), $p = 0.031$. Group differences were not significant; outcome expectations increased for both SG and SG + I groups from baseline to 3-month assessment.

5. Attitude Toward Body Composition-Focused Obesity Management Program

The six items in the attitude questionnaire reflected key topics discussed in every *Total Wellness* class are what make the focus of this study unique to other traditional

weight loss programs. Scores were based on a Likert-type scale from one to 5, with 1 indicating "strongly disagree" and 5 indicating "strongly agree". After recoding, subjects agreed with all of the items for baseline and 3-month assessment, although scores decreased very slightly over time for item 4, which addressed losing body fat as a means for treating overweight/obesity. It must be noted, however, that baseline and 3-month assessment scores for item 4 were the highest of all attitude items, indicating subjects strongly agreed that losing body fat was a positive outcome. Total possible score on the attitude scale was 30. Scores ranged from 14 to 30 for baseline and 17 to 30 for 3-month assessment. Overall, the attitude scores for both study groups were favorable at baseline. While not significant between groups, when collapsed across groups, overall differences between baseline and 3-month assessments were significant. (Refer to Table 1 chapter 4.)

In summary, exercise activity and resistance exercise did increase significantly for more than half of the subjects. Body fat also decreased over time for those subjects in the 3-month assessment aerobic only and aerobic/resistance groups. Therefore, positive changes in exercise behavior were made within the *Total Wellness Program*, related to resistance training. However, based on one-year results, resistance exercise activity decreased while aerobic type increased. It is recommended that for future study, a larger sample of original population take part in the one-year follow-up study and that body fat also be assessed, if possible.

C. Total Wellness Program Evaluations

An evaluation form, for both the SG and SG+I subjects, was included in the post-intervention questionnaires. The questions were specific to the *Total Wellness Program*,

which included the *Total Wellness* class, support group and individual appointments. The questionnaire is included in Appendix H.

1. Objectives and Expectations

The first question of the evaluation form addressed the extent to which the *Total Wellness Program* met the subject's objectives and expectations. This was measured using a 5-point scale that ranged from excellent to very poor. Answers ranged from 'poor' to 'excellent'. Percentage of subjects in each category was poor (14.4), average (23.1), good (34.6), and excellent (26.9).

2. Summary of Expectations

Question two addressed the subject's expectations for the *Total Wellness Program*. The seven choices included topics such as loss of body fat and/or weight, increased muscle mass, cardiovascular and resistance exercise, improved nutrition and knowledge regarding these areas. Subject's choices ranged from selecting only one of the topics to all of the above items. Overall, more than half the subjects (76.2%) indicated 'all the above' addressed their expectations for the *Total Wellness Program.* The remaining subjects (23.8%) indicated at least one of the choices addressed their expectations.

3. Satisfaction of Subjects to Total Wellness Program

The third question asked the subject to express how satisfied they were with the *Total Wellness* classes. The five-item scale ranged from 'extremely satisfied' to 'not satisfied'. Answers ranged from not satisfied (9.6%), not very satisfied (3.8), satisfied (26.9), very satisfied (38.5), to extremely satisfied (21.2).

4. Individual Appointment Satisfaction

If the subject was required to attend any individual appointments as part of the SG+I group (n = 24), they were then asked how satisfied they were with these appointments. Again, the five-item scale ranged from 'extremely satisfied' to 'not very satisfied'. Percentage of subject's answers for each item was not very satisfied (8.4), satisfied (8.4), very satisfied (41.6), and extremely satisfied (41.6).

5. Recommendation to Others

Each subject was asked how likely they would be to recommend the *Total Wellness Program* to others. The five-point scale ranged from 'definitely' to 'definitely not'. Subject's answers ranged from probably not (3.8%), possibly (11.5), very likely (32.7), to definitely (51.9).

6. Summary

Overall, subjects were satisfied with the *Total Wellness Program* and the individual appointments and would recommend this program to others. While there were no significant differences between the SG and SG+I groups on any of the evaluation items, the SG+I subjects indicated slightly more of their expectations and objectives were met, they were more satisfied with the *Total Wellness Program* and, they were more likely to recommend the *Total Wellness Program* to others. The lectures in both the *Total Wellness* class and support groups were based on key items specific to the *Total Wellness Program*. These included focus on body composition change instead of weight loss, resistance training to increase muscle mass, and eating a balanced diet. Support group lectures built upon these topics while individual appointments again focused on these areas, but specific to the subject's needs.

This current study not only tested the effects of the *Total Wellness Program* on self-efficacy, outcome expectations, movement within the stages of change, as well as attitude and exercise behaviors, but also pilot tested the internal reliability of four instruments focused on a body composition focused obesity treatment program. Most of these instruments had good reliability scores, except for the attitude instrument. Further research is needed to assess the intervention in other populations, as well as gaining a larger sample of subjects within the study.

CHAPTER 6

CONCLUSION AND RECOMMENDATIONS

A. Conclusion

A clinic based intervention program focused on body composition versus weight change, was successful at promoting significant body composition change in 19% of the female subjects. While overall changes were not significant between the support group only (SG) and support group plus individual appointment group (SG+I) groups, when groups were combined, stage of change, outcome expectations, attitude and days per week spent exercising improved significantly from baseline to at least the 3-month assessment. The current study demonstrates that a body composition focused obesity management program can be successful at promoting a change in body composition. However, in agreement with other obesity management studies, the significant improvement may be evident in only a small population.

B. Recommendations

1. For Research

This study was the first stage of research to explore the effectiveness of a body composition focused intervention for obesity management. Therefore, it is recommended that further research measure the effectiveness of this obesity intervention in other populations, such as men or adolescents. The instruments developed for this study can be used in other populations. However, because the self-efficacy, outcome expectations, attitude, and exercise behavior questionnaires are specific to the *Total Wellness Program* curriculum, it may be necessary to customize the questions to the specific setting desired.

Comparison of the effectiveness of this intervention with a weight loss focused intervention may shed some light on areas needing improvement to produce significant results from a body composition focused intervention. It may be necessary for a body composition focused intervention to be more structured, planning resistance exercise sessions for the participants on a routine schedule. However, because this was the beginning research of a body composition focused intervention, these changes are suggested for further research.

Length of this study was three months, as compared with similar studies that addressed weight change and stage of change over at least a 6-month study period (Riebe et al., 2003; Sbrocco et al., 1999). It is recommended that for future study, the period between the baseline and post-intervention follow-up be at least 6 months to allow for more possible changes in body composition to take place.

Lastly, a post-hoc one-year follow-up was conducted. Because this follow-up was added to the design of the study after subjects had completed the 3-month *Total Wellness Program* intervention, to improve subject participation, it is recommended that a one-year a follow-up be part of the initial design.

2. For Practice

Results from this study provide an approach to obesity management that improved attitude toward resistance training exercise and progression through the stages of change, and changed outcome expectations to focus on body composition changes related to obesity management. With this improvement in attitude and a positive progression through the stages of change, actions taken toward resistance training are more likely to occur following this body composition focused intervention.

Similar to another obesity management study (Riebe et al., 2003), a subgroup of the study population (19%) did show significant decreases in body fat from baseline to post-intervention. Incorporation of this body composition focused intervention into a weight loss focused setting may improve overall effectiveness by capturing a larger population subset of individuals who improve their obesity status, based on body composition and/or weight.

Furthermore, the questionnaires used in this study were designed to reflect specific areas addressed in the *Total Wellness* classes such as a change in focus from weight lost to body composition change, adding resistance exercises, eating a diet balanced in carbohydrates, proteins and fats and increasing body weight by increasing body muscle. These questionnaires may serve as useful tools in future studies.

While the overall effect of this intervention did not show significant changes in body composition, the subset of nine women who did lose a significant percentage of body fat can be viewed as a positive change. Incorporation of this body composition focused intervention into a weight loss focused setting may improve overall effectiveness by capturing a larger population subset successful at obesity management.

Combination of the body composition focused obesity management program with a supervised resistance training exercise program may provide additional support to subjects taking part in the lifestyle change. This may lead to significant improvements outcome expectations, attitude, self-efficacy and exercise behavior. The supervised resistance training exercise program could take place in a local gymnasium allowing for a varied array of resistance and aerobic exercise. The resistance training exercise sessions

could be lead by a preventive care specialist, which would provide the participants with specialized instruction for resistance exercise and body composition change.

It is strongly recommended that, during any further body composition focused obesity management intervention, regular interaction take place between the participant's physician and the preventive care specialist. This would allow for a team approach specific to the participant's medical and physical needs.

Effective for both practice and further research, use of the waist, hip circumference ratio may provide another form of obesity and health assessment tool. This assessment would also provide more information to guide the preventive specialist in counseling the participant regarding lifestyle changes.

In summary, a body composition focused intervention, such as the *Total Wellness Program*, may provide overweight and obese participants with insight into increasing muscle mass in order to maintain or improve metabolism important for fat loss. The development and maintenance of a successful body composition focused intervention may require more initial planning. However, once established, this intervention may prove more effective at decreasing fat mass and improving muscle mass in the overweight and obese population than the weight loss focused intervention. Thus, health status may improve combined with the participant's satisfaction related to body pride. Further research is needed to provide overweight and obese participants with the most successful body composition focused obesity intervention possible.

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APPENDIX A

Institutional Review Board Approval Forms

INSTITUTIONAL REVIEW BOARD

OSR # 51159

Initial Approval Notice - Expedited Review

OFFICE OF SPONSORED RESEARCH • 11188 Anderson Street • Loma Linda, CA 92350
(909) 558-4531 (voice) • (909) 558-0131 (fax)

To:	**Helen P. Marshak, PhD**
Department:	**Health Promotion & Education**
Protocol:	*Assessment of a body composition focused obesity treatment*
Date:	07/28/2001

The protocol and consent form for this study were reviewed and approved administratively on behalf of the IRB. This decision includes the following determinations:

1. Risk to research subjects: **Risk - Minimal**
2. Approval period begins **07/28/2001** and ends **07/27/2002.**
3. Conditions of approval are: **<None Specified>**

Consent Form

If a written consent form is required, approval will be indicated by the affixed IRB approval stamp. This now becomes your official consent form for the dates specified and should be used as a master for making the necessary copies.

Adverse Events / Protocol Changes

The IRB should be notified in writing of any modifications to the approved research protocol. All adverse effects, anticipated or not, should be reported to the IRB: serious events should be reported within seven days; all others within 15 days.

Protocol Review

Your protocol is tentatively scheduled for review and renewal at the meeting of the IRB in
To assure uninterrupted approval of this project, you will be sent a status report form to complete and return prior to this date. In addition to reporting the number of subjects enrolled, you may close the study or request renewal at this time.

Records

All records relating to this project, including signed consent forms, must be kept on file for three years following completion of the study.

Please note the PI's name and the OSR number assigned your IRB application (as indicated above) on any future communications with the IRB about this project. Direct all communications to the IRB c/o the Office of Sponsored Research.

Thank you for your cooperation in LLU's shared responsibility for the ethical use of human subjects in research.

Signature of IRB Chair/Vice Chair: _____ Date: 7/28/01

IRB Chair:
G. William Saukel, M.D.
Department of Pathology
(909) 558-4794 Gsaukel@ahs.llumc.edu

IRB Administrator:
Linda G. Halstead, M.A., Assoc. Director
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OSR# 51159

INSTITUTIONAL REVIEW BOARD

Change Request Report

OFFICE OF SPONSORED RESEARCH 11188 Anderson Street Loma Linda, CA 92350
(909) 558-4531 (Voice); (909) 558-0131 (Fax)

From: **Marshak, Helen**
Department: **Health Promotion & Education**
Protocol: **Assessment of a body composition focused obesity treatment**

I. This Change Request is the result of :

Initiated by local(LLU) Investigator.

II. Protocol Change

a. Summary: Request for the addition of 1-year follow-up study for the Total Wellness Class study, consisting of six short questionnaires and voluntary body composition assessments. The Student Investigator will telephone each existing Total Wellness Study subject to inquire whether they would like to participate in this follow-up study. If the subject agrees to participate, the six questionnaires will be mailed to each subject. The subject is requested to complete the mailed informed consent document and the six questionnaires then return them in the addressed stamped envelope to the student investigator. Body composition assessments will be scheduled with the student investigator via phone.

b. Classification of significant change(s):

PROCEDURES

2. Changes in subjects-related intervention(s): Addition of 1-year follow-up consisting of a) six short questionnaires mailed to subjects; b) voluntary assessment of body composition to be scheduled by Student Investigator.

Justification: 1-year follow-up will increase comprehensive assessment of the Total Wellness Class there by improving validity of the study. There are no physical risks above those involved as part of voluntary participation in the Total Wellness Class.

c. Change does not involve an updated Investigator's brochure or supplement.

III. Change(s) in informed consent

Yes a. Change to informed consent process? 1-year follow-up was not mentioned in the original ICD, therefore a new ICD has been designed to outline this collection of follow-up information.

Yes b. Change to informed consent document?

Yes c. Subjects will be re-consented? Description of re-consenting process: New ICD will accompany the six questionnaires mailed to each existing subject who volunteers to participate in this 1-year follow-up study.

IV. Checklist of items to include:

☐ Revised consent documentis attached, with a copy highlighting requested changes.

☑ New consent document for reconsenting is provided.

CERTIFICATION OF PRINCIPAL INVESTIGATOR:"*I have reviewed the above Change Request for completeness and accuracy.*"

Helen H. Marshak 9/6/02

Signature of Principal Investigator Date

INSTITUTIONAL REVIEW BOARD ACKNOWLEDGEMENT and REPORT TO PRINCIPAL INVESTIGATOR.

☑ Change Report is accepted as submitted. Summary will appear in Research Report at conclusion of aproval period.

9/12/02

☐ Further information required, as follows: _____

☐ PI needs consultation with IRB chair

☐ Amendment requires full board review. Please submit 23 copies of this report to IRB to be scheduled on IRB agenda.

_____ 9/12/02

Signature of IRB Representative Date

Re:51159 - Request for the addition of 1-year follow-up study for the Total Wellness Class study, consisting of...

Print this report, verify responses are accurate, obtain signature of PI, and submit to the IRB c/o Office of Sponsored Research, Loma Linda University.

APPENDIX B

Letter to Physicians and Medical Personnel

11451 Anderson Street
Loma Linda CA 92354

July, 2001

RE: Research study involving Beaver Medical Group *Total Wellness Class* Patients

Dear Dr.
I am a Doctorate of Public Health student at Loma Linda University. Recently, I have been interning with Dr. Ernie Medina, DrPH, in the Beaver Medical Group Patient Education Department, Redlands.

Beginning in August 2001, I along with Dr. Ernie Medina, DrPH and Dr. Helen Hopp Marshak, PhD, will be conducting research involving the Beaver Medical Group *Total Wellness Class*, currently offered through the Patient Education Department. We will be assessing body composition, exercise and attitude changes. The research will take place August through December 2001.

In order to proceed with involving Beaver Medical patients, I need to have a **Medical Clearance to Exercise** form (Please see attachment) filled out and signed for all patients referred to the *Total Wellness Class*. Unless otherwise indicated, all patients referred for the *Total Wellness Class*, who have a signed **Medical Clearance to Exercise** form, will be potential participants in this research.

Thank you for your help and continued referrals to the *Total Wellness Class*.

Please contact me regarding any questions or comments.

Beverly Hall, RN, DrPH(c)
Phone: (909)-799-7546
Email: bevdhall@yahoo.com
Loma Linda University, School of Public Health, Health Promotion
Enclosure (1)

LOMA LINDA UNIVERSITY
INSTITUTIONAL REVIEW BOARD
APPROVED 7/25/01 VOID AFTER 7/23/02
#3119 CHAIR

Date: 7/24/01

APPENDIX C

Written Scripts for Telephone Contacts

Loma Linda University

Written Script for Telephone Contact
For
Assessment of a Body Composition Focused Obesity Treatment

Hello, my name is Beverly Hall. I am a Doctorate of Public Health candidate and am calling you from Loma Linda University School of Public Health Department of Health Promotion. The purpose for my call is to inquire whether you would be willing to participate in a research study. The focus of the research is on assessing the Total Wellness Class. This study is an attempt to identify exercise habits and attitude change(s) that may take place during the Total Wellness Class, Total Wellness Support Group classes and individual appointment sessions.

After initial evaluation, you will be administered five questionnaires and undergo assessment of your body composition. The questionnaires and assessments will take approximately two hours.

Would you like to schedule an appointment to discuss the details of the study? At that time, if you agree, we will proceed with the study evaluation and assessment tests.

LOMA LINDA UNIVERSITY
INSTITUTIONAL REVIEW BOARD
APPROVED 7/24/01 VOID AFTER 7/24/02
#3155 CHAIR

Date: 7/24/01

Loma Linda University
School of Public Health

Written Script for Telephone Contact for
Assessment of a Body Composition Focused Obesity Treatment: 1-Year Follow-up
OSR# 51159

Hello, my name is Beverly Hall, the student investigator who you worked with regarding the Total Wellness Class study last year. I am a Doctorate of Public Health candidate and am calling you from Loma Linda University School of Public Health Department of Health Promotion. I am wondering if you would be willing to participate in a 1-year follow-up research study. The purpose of the study is to briefly assess your exercise habits and attitude changes that may have taken place in the year following your participation in the original study.

If you agree to participate, you will be mailed six short questionnaires and have the opportunity to schedule an appointment for the 1 year assessment of your body composition. Completing the questionnaires will take about 15 minutes, and coming in for the assessments will take approximately 15-30 minutes of your time.

Would you like to participate in this 1-year follow-up study?

If yes: I will mail you the informed consent form and six short questionnaires for this follow-up study. Please return them to me within 4 weeks in the enclosed addressed, stamped envelope. Would you like to schedule an appointment for the body composition assessments?

If yes: Date and Time scheduled: _____

If no: thank you for your time.

APPENDIX D

Informed Consent Form

LOMA LINDA UNIVERSITY

School of Public Health

Loma Linda, California 92350
(909) 558-4546
FAX: (909) 558-4087

Informed Consent Document
For
Assessment of a Body Composition Focused Obesity Treatment

Purpose and Procedures of the Study: You are invited to participate in this study because you have been referred to the *Total Wellness Class*. The aim of this study is to evaluate the *Total Wellness Class*. Participation in this study will take 12 weeks.

All Total Wellness enrollees will complete one 2-hour *Total Wellness Class* and two 1-hour *Total Wellness Support Group* classes. Participants in this study may also receive three 30-minute *Total Wellness* individual appointments. Random assignment to *Total Wellness* individual appointments will be based on the flip of a coin.

At the beginning of the study and, 12-weeks later at the end of the study, you:

1) will be asked to complete five questionnaires about your exercise habits and attitudes;

2) will receive two body composition assessments that are part of the standard of care for the *Total Wellness Class*: a) *Tanita* bioelectrical impedance analysis and b) skin fold measurement.

At the beginning of the study, you will also be given exercise activity worksheets to record your exercise over the 12-week period.

Length of testing including questionnaires, bioelectrical impedance analysis, and skin fold measurement will be approximately 2 hours at each of the two testing times.

Costs and Payments to the Participant: There is no cost for participation in this study.

Risks: There are no physical risks above those involved as part of routine participation in *the Total Wellness Class* and *Total Wellness Support Group*.

Benefits: Outside of completing the *Total Wellness Class* and *Total Wellness Support Group* classes, it is unlikely you will personally benefit from this study but your assistance will tell us whether the Total Wellness program can better achieve its goals in any way.

Confidentiality: Information obtained in this study is strictly confidential unless disclosure is required by law. Your name will not be used in the reporting of information in publications or conference presentations. The results of this study will be reported in terms of treatment groups, not terms of individuals.

_____ Initial
_____ Date

LOMA LINDA UNIVERSITY
INSTITUTIONAL REVIEW BOARD
APPROVED 7/28/01 VOID AFTER 7/27/2002
#5115 CHAIR

Participant's Rights to Withdraw from the Study: Participation in this study is voluntary. Your decision whether or not to participate or terminate at any time will not affect your present or future medical care, including your involvement in the Total Wellness program.

Impartial Third Party Contact: If you wish to contact an impartial third party not associated with this study regarding any question or complaint you may have about the study, you may contact the Office of Patient Relations, Loma Linda University Medical Center, Loma Linda, CA 92354, phone (909) 558-4647 for information and assistance.

Informed Consent Statement: "I have read the contents of the consent form and have listened to the verbal explanation given by the investigator. My questions concerning this study have been answered to my satisfaction. I hereby give voluntary consent to participate in this study. Signing this consent document does not waive my rights nor does it release the investigators, institution or sponsors from their responsibilities. I may call the Student Investigator, Beverly Hall, at (909)-799-7546."

_____ _____

Signature of Subject Date

_____

Signature of Witness

Copy of Consent upon Signature: "I have been given a copy of this consent form and the California Experimental Subject's Bill of Rights."
_____ Participant's Initials

Investigator Signature: "I have reviewed the contents of the consent form and the California Experimental Subject's Bill of Rights with the person signing above. I have explained potential risks and benefits of the study."

_____ _____ _____

Signature of Investigator Phone Number Date

LOMA LINDA UNIVERSITY
INSTITUTIONAL REVIEW BOARD
APPROVED [illegible] VOID AFTER [illegible]
#[illegible] CHAIR [illegible]

APPENDIX E

Physical Activity Readiness Questionnaire

PAR-Q: An Exercise Safety Quiz

For most people physical activity should not pose any problem or hazard. PAR-Q has been designed to identify the small number of adults for whom physical activity might be inappropriate or those who should have medical advice concerning the type of activity most suitable for them.
Common sense is your best guide in answering these few questions. Please read them carefully and check the yes or no opposite the question if it applies to you.

	YES	NO	
1.	○	○	Has your doctor ever said you have heart trouble?
2.	○	○	Do you frequently have pains in your heart and chest?
3.	○	○	Do you often feel faint or have spells of severe dizziness?
4.	○	○	Has a doctor ever said your blood pressure was too high?
5.	○	○	Has your doctor ever told you that you have a bone or joint problem such as arthritis that has been aggravated by exercise, or might be made worse with exercise?
6.	○	○	Is there a good physical reason not mentioned here why you should not follow an activity program even if you wanted to?
7.	○	○	Are you over age 65 and not accustomed to vigorous exercise?

If you answered YES to one or more questions...

If you have not recently done so, consult with your personal physician by telephone or in person before increasing your physical activity and/or taking a fitness test.

If you answered NO to all questions...

If you answered PAR-Q accurately, you have reasonable assurance of your present suitability for an exercise test.

APPENDIX F

Baseline and Three-Month Post-Intervention Study Questionnaires

Resistance Training Behavior Questionnaire

Resistance Training: Defined as any exercise that increases body muscle and muscle strength.
Examples include weight lifting, sit-ups, push-ups, lifting dumb bell weights, rubber bands workouts.

Instructions: Please circle the number that most accurately describes your current resistance training behavior:

1	"I currently do not participate in resistance training and do not plan to start resistance training in the next 6 months."
2	"I currently do not participate in resistance training, but I have been thinking about starting to resistance train within the next 6 months."
3	"I currently do some resistance training, but not regularly (equal to 3 or more days per week for 20 minutes or more each day)."
4	"I currently participate in resistance training on a regular basis (equal to 3 or more days per week for 20 minutes or more each day), but I have only been doing so within the past 6 months."
5	"I currently participate in resistance training on a regular basis (equal to 3 or more days per week for 20 minutes or more each day) and have been doing so for longer than 6 months."

Confidence Questionnaire

Instructions: Please circle the number that most accurately reflects how confident you are that you could participate in resistance training exercise in each of the following situations:

	not at all confident				extremely confident
When I am tired.	1	2	3	4	5
When I am in a bad mood.	1	2	3	4	5
When I feel I don't have time.	1	2	3	4	5
When I am on vacation.	1	2	3	4	5
When it is hot outside.	1	2	3	4	5
When I must do it by myself.	1	2	3	4	5
When I want to relax.	1	2	3	4	5
When I feel anxious.	1	2	3	4	5
When I have had a change in my daily schedule.	1	2	3	4	5

Results Questionnaire

Instructions: Please circle the number that most accurately reflects the results that you expected by participating in the Total Wellness program:

	Strongly disagree	Disagree	Undecided	Agree	Strongly agree
Increase my body muscle.	1	2	3	4	5
Decrease my body fat.	1	2	3	4	5
Change the amount I weigh on the scales.	1	2	3	4	5
Keep my body muscle the same so I do not gain more weight on the scales.	1	2	3	4	5
Increase the time I spend Participating in resistance training.	1	2	3	4	5
Increase the amount of time I spend doing aerobic exercise.	1	2	3	4	5
Learn to eat a variety of healthy foods including carbohydrates, proteins, and fats.	1	2	3	4	5
Learn to eat a very low calorie diet that does not include carbohydrates.	1	2	3	4	5

Attitude Questionnaire

Instructions: Please circle the number that most closely indicates how you feel about each of the following statements:

Treating my overweight or obesity condition means:	Strongly disagree	Disagree	Undecided	Agree	Strongly agree
possibly increasing the amount I weigh on the scales by adding body muscle.	1	2	3	4	5
keeping my body muscle the same so I do not gain more weight on the scales.	1	2	3	4	5
adding body muscle through resistance training.	1	2	3	4	5
losing body fat.	1	2	3	4	5

Current Exercise Behavior Questionnaire

Instructions: Please answer the following questions regarding your current exercise activity.

1) During the past week, how many days have you exercised? (circle correct number)

0 1 2 3 4 5 6 7

2) During the past week, what is the average time PER DAY you have spent exercising?

0-15 minutes 15-30 minutes 30-45 minutes

45-60 minutes more than 60 minutes

3) During the past week, what type(s) of exercise have you participated in:

O None

O Aerobic (examples include walking, jogging, swimming, team sports, stair climbing, aerobics)

O Resistance training (examples include weight lifting, strength training, working with rubber bands, sit-ups)

APPENDIX G

One-Year Follow-Up Questionnaires

Resistance Training Behavior Questionnaire

Resistance Training: Defined as any exercise that increases body muscle and muscle strength.
Examples include weight lifting, sit-ups, push-ups, lifting dumb bell weights, rubber bands workouts.

Instructions: Please circle the number that most accurately describes your current resistance training behavior:

1	"I currently do not participate in resistance training and do not plan to start resistance training in the next 6 months."
2	"I currently do not participate in resistance training, but I have been thinking about starting to resistance train within the next 6 months."
3	"I currently do some resistance training, but not regularly (equal to 3 or more days per week for 20 minutes or more each day)."
4	"I currently participate in resistance training on a regular basis (equal to 3 or more days per week for 20 minutes or more each day), but I have only been doing so within the past 6 months."
5	"I currently participate in resistance training on a regular basis (equal to 3 or more days per week for 20 minutes or more each day) and have been doing so for longer than 6 months."

Confidence Questionnaire

Instructions: Please circle the number that most accurately reflects how confident you are that you could participate in resistance training exercise in each of the following situations:

	not at all confident				extremely confident
When I am tired.	1	2	3	4	5
When I am in a bad mood.	1	2	3	4	5
When I feel I don't have time.	1	2	3	4	5
When I am on vacation.	1	2	3	4	5
When it is hot outside.	1	2	3	4	5
When I must do it by myself.	1	2	3	4	5
When I want to relax.	1	2	3	4	5
When I feel anxious.	1	2	3	4	5
When I have had a change in my daily schedule.	1	2	3	4	5

Attitude Questionnaire

Instructions: Please circle the number that most closely indicates how you feel about each of the following statements:

Treating my overweight or obesity condition means:	Strongly disagree	Disagree	Undecided	Agree	Strongly agree
possibly increasing the amount I weigh on the scales by adding body muscle.	1	2	3	4	5
keeping my body muscle the same so I do not gain more weight on the scales.	1	2	3	4	5
adding body muscle through resistance training.	1	2	3	4	5
losing body fat.	1	2	3	4	5

Current Exercise Behavior Questionnaire

Instructions: Please answer the following questions regarding your current exercise activity.

1) During the past week, how many days have you exercised? (circle correct number)

0 1 2 3 4 5 6 7

2) During the past week, what is the average time PER DAY you have spent exercising?

0-15 minutes 15-30 minutes 30-45 minutes

45-60 minutes more than 60 minutes

3) During the past week, what type(s) of exercise have you participated in:

O None
O Aerobic (examples include walking, jogging, swimming, team sports, stair climbing, aerobics)
O Resistance training (examples include weight lifting, strength training, working with resistance bands, sit-ups)

4) What exercise activity has **increased** over the past 12 months?

O None
O Aerobic (examples include walking, jogging, swimming, team sports, stair climbing, aerobics)
O Resistance training (examples include weight lifting, strength training, working with resistance bands, sit-ups)

5) What exercise activity has **decreased** over the past 12 months?

O None
O Aerobic (examples include walking, jogging, swimming, team sports, stair climbing, aerobics)
O Resistance training (examples include weight lifting, strength training, working with resistance bands, sit-ups)